

2013

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Recommended Citation

Fitzpatrick, Ethan R., "Open Source Synthetic Biology: Problems and Solutions" (2013). *Law School Student Scholarship*. 47.
https://scholarship.shu.edu/student_scholarship/47

Open Source Synthetic Biology: Problems and Solutions
Ethan R. Fitzpatrick*

I. Introduction

In May 2010, the J. Craig Venter Institute announced the creation of a simple bacterial cell entirely controlled by a chemically synthesized genome.¹ The scientists started with the digital information of the organism's genomic DNA sequence and chemically synthesized one nucleotide at a time, the full 1.08 million base pairs that made up the organisms genome.² The synthetic genome was then inserted into a host bacterium that had its native DNA removed.³ The resulting man-made bacterium was able to replicate itself using only the synthetic genome.⁴ Advances in the ability to synthesize genome-length strands of DNA have coincided with a growing understanding of the functions of individual genes and gene networks.⁵ With the available knowledge of how whole genomes function and the technical capability of synthesizing whole genomes, it will be possible to digitally design novel organisms to perform some desired function and then manifest that synthetic organism in the real world.⁶ Creation of the first synthetic organism provided "a proof of principle for producing cells based on computer-designed genome sequences. DNA sequencing of a cellular genome allows storage of the

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¹ D.G. Gibson et al., *Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome*, 329 SCIENCE 52 (2010).

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ Matthias Heinemann & Sven Panke, *Synthetic Biology—Putting Engineering Into Biology*, 22 BIOINFORMATICS 2790 (2006).

⁶ See Gibson et al., *supra* note 1.

genetic instructions for life as a digital file.”⁷ “The approach we have developed should be applicable to the synthesis and transplantation of more novel genomes as genome design processes.”⁸

This ultimate goal of designing novel synthetic organisms using the technology of synthetic biology sounds like pure science fiction, but it is entirely possible and would have an enormous impact on biotechnology and medicine. Synthetic organisms might be designed to create new sources of food, fuel, and medicine that current technology is not capable of producing. Additionally, these benefits will arrive with incredible speed, efficiency, and cost effectiveness. Designing wholly novel synthetic organisms is still on the horizon, however, and presently scientists are left with a combination of older methods to innovate in the field of biotechnology, or more recently, the emerging technology of synthetic biology in its earliest phase. In order to make the possibilities of synthetic biology a reality in the least amount of time, one organization—the BioBricks Foundation—is attempting to protect this emerging field from the potential stifling effects of DNA-patents by establishing an open source movement.⁹ The hope is that an open-source synthetic biology commons would encourage innovation in ways similar to the wildly successful open source software movement.¹⁰ Towards that end, a similar open-source approach to synthetic biology might be useful.¹¹ The world of synthetic biology, however, poses unique problems to the establishment of an open source movement. These problems include incentivizing entities to participate, maintaining openness once it is established, and creating useable biomedical products.

⁷ *Id.* at 52.

⁸ *Id.*

⁹ *About the BioBricks Foundation*, BIOBRICKS.ORG, <http://biobricks.org/about-foundation/> (last visited Feb. 11, 2012).

¹⁰ *Id.*

¹¹ *Id.*

Part II of this Comment provides an overview of the technology of synthetic biology and explains why it is important. Part III introduces the current movement towards open source synthetic biology, as established by the BioBricks Foundation, and Part IV describes the past strategies used to establish and maintain other analogous open-source biotechnology movements. Three specific strategies are discussed: a copyright approach, a contract-based approach, and a patent-based approach to establish and maintain a commons. Part V then assesses whether these approaches to maintaining a synthetic biology commons are possible, and if so, what problems might be unique to synthetic biology. Part VI then proposes a wholly novel strategy to advance the progress of synthetic biology. This strategy uses an open-source/property-right hybrid approach, under the auspices of a standard setting organization, in order to overcome problems that cannot be addressed under the three previously described strategies. The Comment then concludes.

II. Synthetic Biology: What is it and Why is it?

A. Recombinant DNA technology laid the foundation for genetic engineering.

Deoxyribonucleic acid (DNA) is the molecule which encodes the instructions for life.¹² The DNA language uses four nucleotides—adenine, thymine, cytosine, and guanine—organized in specific sequences to compose the genes responsible for heritable traits.¹³ The DNA sequence of an organism gets copied with an extremely high fidelity, averaging only one nucleotide error

¹² BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 193 (4th ed. 2002).

¹³ *Id.* at 194.

for every billion nucleotides copied.¹⁴ This DNA sequence is passed on to offspring, transmitting genetic information from generation to generation.¹⁵

Scientists have been tinkering with DNA since 1972, when Paul Berg, Stanley Cohen, and Hubert Boyer, discovered a way to cut and paste pieces of DNA together.¹⁶ This was followed by many further advances in manipulating sequences of DNA, such as the invention of the “polymerase chain reaction” (used to amplify pieces of DNA), rapid sequencing technology, and targeted gene replacement.¹⁷ Before the development of these technologies, the sheer size and chemical-repetitiveness of DNA made it one of the most difficult molecules to study and manipulate.¹⁸ The advent of the above methods, however, now makes DNA one of the easiest molecules to manipulate.¹⁹ Presently, the technology has reached a level of such sophistication that scientists routinely recombine the DNA sequences within a species (or even between species), resulting in novel DNA sequences that do not exist in nature.²⁰ This “recombinant DNA technology” (rDNA technology) has had numerous applications as far reaching as medicine, research, and agriculture.²¹ Despite these advances, however, scientists have been limited by rDNA technology.²² Generally, rDNA techniques involve manipulating a small

¹⁴ *Id.* at 236.

¹⁵ *Id.* at 195.

¹⁶ *Id.* at 492.

¹⁷ *Id.*

¹⁸ ALBERTS ET AL., *supra* note 7, at 491.

¹⁹ *Id.*

²⁰ *Id.* at 493.

²¹ M.J. The, *Human Insulin: DNA Technology's First Drug*, AMERICAN JOURNAL OF HOSPITAL PHARMACY (Nov. 1989) (mass production of human insulin as a replacement for insulin derived from animal sources); ALBERTS ET AL., *supra* note 7 (rDNA technology has been used in the classification of genes/proteins and studying regulatory networks of genes); *Roundup Ready System*, MONSANTO.COM, <http://www.monsanto.com/weedmanagement/Pages/roundup-ready-system.aspx> (last visited Feb. 11, 2012) (genetically modified plants developed using rDNA technology increase crop yields).

²² See e.g., S. Cheng, C. Fockler, W.M. Barnes & R. Higuchi, *Effective Amplification of Long Targets From Cloned Inserts and Human Genomic DNA*, 91 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 5695 (1994) (It is possible to PCR amplify sequences of DNA up to approximately forty-thousand bases. For comparison, the human genome is billions of bases long).

number of genes and each modification involves a very time consuming procedure.²³ This limitation, together with a very superficial understanding of how genes work alongside one another, has resulted in most scientific advances using rDNA technology involving the engineering of a single gene.²⁴ For example, recombinant human insulin, which has almost entirely replaced insulin derived from animal sources,²⁵ is synthesized by expressing a single human insulin gene in the bacteria *E. Coli*.²⁶ In the specific case of human insulin production, manipulation of a single gene is sufficient to achieve the desired result; creating an alternative source of insulin for people with diabetes.²⁷ In some situations, however, manipulating single genes is not sufficient and in those cases the emerging technology of synthetic biology is allowing scientists to move beyond the limitations imposed by recombinant DNA techniques.

B. Defining the New Technology of Synthetic Biology

Defining synthetic biology is not easy. There is no bright line that distinguishes the older rDNA technology from the new synthetic biology.²⁸ The term has arisen in light of advanced techniques for chemically synthesizing sequences of DNA, along with a growing understanding of how multiple genes work in groups to form “gene networks” or “gene circuits.”²⁹ Thus, it is not surprising that the term means something different depending on one’s technical background.

²³ See e.g., Bruce A. Roe et al., *Protocols for Recombinant DNA Isolation, Cloning, and Sequencing*, http://www.genome.ou.edu/protocol_book/protocol_index.html (last visited Apr. 7, 2012) (even the simplest cloning procedure involves many steps and will take several days to complete).

²⁴ Subin Mary Zachariah & Leena K. Pappachen, *A Study of Genetic Engineering Techniques In Biotechnology Based Pharmaceuticals*, 3 THE INTERNET JOURNAL OF NANOTECHNOLOGY 1 (2009), available at <http://www.ispub.com/journal/the-internet-journal-of-nanotechnology/volume-3-number-1/a-study-of-genetic-engineering-techniques-in-biotechnology-based-pharmaceuticals.html>.

²⁵ The, *supra* note 15.

²⁶ *Id.*; *Insulin recombinant*, DRUGBANK.CA, <http://www.drugbank.ca/drugs/DB00030> (last visited Nov. 5, 2011).

²⁷ The, *supra* note 15.

²⁸ See Drew Endy, *Foundations for Engineering Biology*, 24 NATURE 449 (2005).

²⁹ Jeff Hasty, David McMillen & J.J. Collins, *Engineered Gene Circuits*, 420 NATURE 224, 224 (2002).

Drew Endy, one of the pioneers of synthetic biology, states that for the biologist, the term means “the ability to design and construct synthetic biological system [to] provide a direct and compelling method for testing our current understanding”³⁰ For the chemist, synthetic biology “is an extension of synthetic chemistry[:] the ability to create novel molecules and molecular systems [to allow] the development of useful diagnostic assays and drugs, expansion of genetically encoded functions, [and] study of the origins of life”³¹ For the group of people Endy terms “re-writers,” the term means that “the genomes encoding natural biological systems can be ‘re-written,’ producing engineered surrogates that might usefully supplant some natural biological systems.”³² And finally, for engineers, synthetic biology is an attempt “to combine a broad expansion of biotechnology applications with . . . an emphasis on the development of foundational technologies that make the design and construction of engineered biological systems easier.”³³

For the purposes of this Comment, the technology of synthetic biology is summarized as follows: Advances in the ability to chemically synthesize sequences of DNA, plus a growing understanding of how genes function singularly and in groups, allowing scientists to treat genes as biological *parts* that they can use to engineer a living organism—much like an engineer would use various parts to build a car. This Comment adopts this definition of synthetic biology because the technological capability of designing standardized biological parts is necessary for the establishment of open-source synthetic biology.³⁴ The definition is largely drawn from

³⁰ Endy, *supra* note 28.

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ See David W. Opderbeck, *The Penguin’s Genome, or Coase and Open Source Biotechnology*, 18 HARV. J.L. & TECH. 167 (2004). Professor Opderbeck reviews the aspects of a technology that make it amenable to an “open source” project. It must be possible to break the project into components and each component must be manageably

Endy's engineering perspective of synthetic biology in order to stress the importance of composable biological parts that individuals can design and then contribute to a synthetic biology commons. Also, this definition emphasizes that the difficulty or ease with which scientists can create biological parts will be an important factor in the success or failure of a synthetic biology commons.³⁵

C. Faster, Easier Genetic Engineering *via* Synthetic Biology

One of the underlying goals of synthetic biology is to make genetic engineering faster and easier.³⁶ This goal can only be reached if standardized tools and methods are established that make genes and gene networks function predictably and reliably. Unfortunately, current rDNA techniques largely lack any kind of standardization, which severely reduces the pace of technological innovation.³⁷ An analogy might be building a car from scratch—starting with screws and a screw driver, finishing with a fully functional car. An engineer with established tools and parts can build a car from scratch with little difficulty because the function of each part is known and standards are in place for parts to work together. But imagine the challenge of building a car from scratch not knowing how each part works or whether individual parts can work together. Without standard parts and tools, the builder would work by trial and error,

small. With this in mind, I emphasize the development of discrete biological parts in my definition of synthetic biology.

³⁵ *See id.* Professor Operbeck points out that rDNA technology poses some technical problems with respect to component “layers” in the context of open source biotechnology. For example, manipulating DNA requires specialized equipment and expertise. Advances in synthetic biology, however, might significantly lower this open source barrier. Specifically, advances in DNA synthesis methods have the potential to make manipulating DNA sequences easy, fast, cheap, and without formal training. Standardization of biological parts may also fulfill the need for a common biotechnology platform. Professor Operbeck also notes that to establish open source biotechnology, there must exist social-psychological rewards and a community of contributors with authoritative voices. While these two factors are outside the scope of this Comment, the BioBrick Foundation could arguably be in the initial stages of fulfilling these needs.

³⁶ Reshma P. Shetty, Drew Endy, & Thomas F. Knight, *Engineering BioBrick Vectors from BioBrick Parts*, 2 JOURNAL OF BIOLOGICAL ENGINEERING 1, 1 (2008), available at <http://www.jbioleng.org/content/2/1/5>

³⁷ *See* Endy, *supra* note 28.

resulting in a significantly longer time to completion. This problem is compounded in the context of a living organism—biological systems are far more complex than a car, and every biological part has the opportunity to interact with every other biological part. Presently, all engineering of novel gene networks requires a significant amount of trial and error during development. For this reason, without standardized biological parts, the pace of innovation will be glacial.

To make this point, Endy uses the example of creating a biological oscillator.³⁸ An electrical engineer could create several working ring oscillators in under an hour.³⁹ In contrast, it took two of the world's best biophysicists a year to make an analogous biological oscillator.⁴⁰ The difference is that electrical engineers have standard parts available to them that work predictably and reliably, while people working in the biological sciences do not.⁴¹ If synthetic biological techniques are used to make molecular biology more like an engineering discipline, it will rapidly increase the rate at which scientists create biotechnology-related products and therapies.

One area that would benefit from an increase in the pace of progress is in the field of medicine. Recently, scientists have taken a synthetic biology approach to engineer biological systems as novel therapies in a pre-clinical setting.⁴² For example, scientists engineered a bacteriophage (a virus that infects bacterium) that can destroy bacterial biofilms resistant to antibiotics.⁴³ Another example is a bacteria engineered to invade cancer cells in a solid tumor.⁴⁴

³⁸ Warren C. Ruder, Ting Lu, & James J. Collins, *Synthetic Biology Moving into the Clinic*, 333 *SCIENCE* 1248, 1249 (2011).

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ See Endy, *supra* note 28.

⁴² See Ruder, Lu & Collins, *supra* note 38.

⁴³ *Id.*

⁴⁴ *Id.*

A synthetic organism is even being developed to modify the “human microbiome,” the endogenous ecosystem of bacteria found in all healthy people which is required for normal physiology.⁴⁵ Scientists are engineering the microbiome bacterium to live in the human gut with the ability to prevent the secretion of toxins from cholera.⁴⁶ Other bacteria have been engineered to secrete various factors to treat diabetes or HIV.⁴⁷ Scientists may even be able to engineer a laboratory mosquito that is resistant to hosting malaria and that would be able to pass the resistance trait into the natural population of mosquitoes.⁴⁸

All of these advances were the result of manipulating genomes by removing and/or adding various parts to alter biological pathways.⁴⁹ These first few attempts at controlling the behavior of an organism with synthetic biology techniques—by manipulating a relatively modest number of genes—is useful for animal studies.⁵⁰ But in order to be possible in human beings, it “may be necessary to identify entirely new modules and components from endogenous networks as well as to synthesize and characterize diverse component libraries.”⁵¹ In order to support human application, the degree of control over the behavior of synthetic organisms will have to increase dramatically.⁵² There is a strong motivation to advance the technology of synthetic biology as fast as possible given the immense promise in the field of medicine. The quicker that scientists make advances, the sooner they will develop wholly novel therapies to treat human disease.

⁴⁵ *Id.*

⁴⁶ *Id.* at 1249.

⁴⁷ Ruder, Lu, & Collins, *supra* note 38, at 1249

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* at 1251.

⁵² *See* Ruder, Lu, & Collins, *supra* note 38.

III. Advancing Genetic Engineering Through Open-Source Synthetic Biology

The benefits of synthetic biology's engineering principles are clear: faster, easier, and more novel solutions to the world's biologically addressable problems. But the question remains: Once standard biological parts are created, how should they be used in order to foster innovation? Currently, gene patents dominate the biotechnology landscape.⁵³ Literally tens of thousands of human genes are patented by various companies who solely own the patent rights to use them.⁵⁴ Many commentators have posited that these patent rights slow the pace of progress dramatically.⁵⁵ Emerging technologies are, by their very nature, especially vulnerable to broad patents that suppress innovation.⁵⁶ Some commentators fear that "foundational patents" (also known as "upstream patents"), which are patents that cover an essential aspect of a technology and are usually very broad in scope, will stifle the development of synthetic biology, along with all of its potential benefits to mankind.⁵⁷ This is because the technology that a foundational patent covers is necessarily incorporated into any downstream research or resulting product.⁵⁸

One response addressing the potential threat of patents inhibiting synthetic biology innovation is to establish a synthetic biology commons where standard biological parts are made freely available to all.⁵⁹ Once foundational biological parts are made publicly available in such a commons, individual entities would not have the right to patent them.⁶⁰ Furthermore, some

⁵³ See Sam Kean, *The Human Genome (Patent) Project*, 331 SCIENCE 530 (2011).

⁵⁴ *Id.* at 531.

⁵⁵ See Micheal A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) (patents over various biomedical technologies may result in an "anticommons" where intellectual property rights result in underutilization of technology that hinders advancement).

⁵⁶ *Id.*

⁵⁷ See Heller & Eisenberg, *supra* note 55, at 698; Sapna Kumar and Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745, 1757 (2007).

⁵⁸ See Heller & Eisenberg *supra* note 55, at 698.

⁵⁹ Joachim Henkel & Stephen M. Maurer, *The Economics of Synthetic Biology*, 3 MOLECULAR SYSTEMS BIOLOGY 1, 3-4 (2007), available at <http://www.nature.com/msb/journal/v3/n1/full/msb4100161.html>.

⁶⁰ 35 U.S.C. § 102(a)

commentators have argued that this strategy has the added benefit of encouraging innovation.⁶¹ This “open-source” approach to synthetic biology is analogous to the open-source software movement which was wildly successful and resulted in the creation of countless computer applications including the Linux operating system.⁶²

The following subsections examine what it means to be “open-source” and how those open-source principles are currently applied to the emerging technology of synthetic biology. One organization in particular, the BioBricks Foundation, has been established in an initial attempt to launch an open-source community.⁶³ Part III. A will describe what it means to be “open-source,” and the terms used to maintain openness in the context of computer software. Part III. B will discuss the open-source strategy of the BioBricks Foundation, and Part III. C will consider the problems associated with maintaining openness.

A. Open Source

The term “open source” has become strongly associated with computer software code that is made freely available for individual use and modification.⁶⁴ The principles that open-source computer programmers established, however, are applicable to other technologies, including synthetic biology. The Open Source Initiative (OSI), which uses the term in the software context, defines “open source” as terms of distribution that comply with specific criteria.⁶⁵ The OSI uses ten different terms of distribution, all of them written with software

⁶¹ Andrew W. Torrance, *Synthesizing Law For Synthetic Biology*, 11 MINN. J. L. SCI. & TECH. 629, 650–51 (2010).

⁶² *Id.* at 654.

⁶³ *About the BioBricks Foundation*, BIOBRICKS.ORG, <http://biobricks.org/about-foundation/> (last visited Feb. 11, 2012).

⁶⁴ *Open Source Definition*, OPENSOURCE.ORG, <http://www.opensource.org/osd.html> (last visited Feb. 11, 2012).

⁶⁵ *Id.*

development in mind.⁶⁶ But each term can be applied to other technologies where non-rivalrous information⁶⁷ is being freely distributed, including the technology of synthetic biology. The most important OSI requirements with respect to maintaining openness are: allowing free redistribution, allowing derived works, and allowing a distribution of licenses.⁶⁸ The free redistribution term requires that a “license shall not restrict any party from selling or giving away the software as a component of an aggregate software distribution containing programs from several different sources. The license shall not require a royalty or other fee for such sale.”⁶⁹ The derived-works term states that “the license must allow modifications and derived works, and must allow them to be distributed under the same terms as the license of the original software.”⁷⁰ And the distribution of license term states that “the rights attached to the program must apply to all to whom the program is redistributed without the need for execution of an additional license by those parties.”⁷¹ Importantly, software developers writing computer code have the intellectual property rights—in copyright law—that are required to impose these terms on others who would use their works.⁷² The BioBricks Foundation is a pioneering institution that is actively seeking to establish an open source biotechnology community by applying open source principles to the emerging field of synthetic biology.⁷³

⁶⁶ *Id.*

⁶⁷ See Opderbeck, *supra* note 34, at 207–08. (“[I]nformation commons theorists hold that information is non-rivalrous because an infinite number of people can simultaneously think the same idea without diminishing the idea’s content.”)

⁶⁸ *Open Source Definition*, *supra* note 64.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² 17 U.S.C. § 101 (Literary works include words, numbers, or other indicia, regardless of the nature of its embodiment).

⁷³ *The BioBricks Foundation works to ensure that the engineering of biology is conducted in an open and ethical manner to benefit all people and the planet*, BIOBRICKS.ORG, <http://biobricks.org> (last visited Feb. 11, 2012) (“We are dedicated to advancing synthetic biology to benefit all people and the planet. To achieve this, we must make engineering biology easier, safer, equitable, and more open. We do this in the following ways: by ensuring that the

B. BioBricks Foundation

The BioBricks Foundation is an organization established to advance the field of synthetic biology “by ensuring that the fundamental building blocks of synthetic biology are freely available for open innovation.”⁷⁴ Toward that end, the BioBricks Foundation has established the first synthetic biology commons where various DNA “parts” are made freely available for public use, applying open-source software principles.⁷⁵

With the goal of openness in mind, the foundation has created User/Contributor contracts—collectively titled “BioBricks Public Agreement”—to promote the use and innovation of BioBricks parts.⁷⁶ The terms of the BioBricks Public Agreement are meant to ameliorate the threat of patent rights over BioBricks parts in an attempt to promote their open and free use.⁷⁷ The main goal of this open strategy is to “accelerate the pace of innovation, collapse development timelines and speed time-to-market of inventive synthetic biology-based solutions while fostering the ethical use of the technology.”⁷⁸ The contracts contain some terms that are analogous to OSI open source terms of distribution.⁷⁹ The BioBricks Public Agreement is described as “a scalable contract among parties”—a contract “between one person who wants to make a genetically encoded function free to use and someone who wants to use it freely.”⁸⁰

fundamental building blocks of synthetic biology are freely available for open innovation; by creating community, common values and shared standards; and by promoting biotechnology for all constructive interests.”)

⁷⁴ *Id.*

⁷⁵ *FAQ*, BIOBRICKS.ORG, <http://biobricks.org/faq/> (last visited Feb. 11, 2012).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *About the BioBricks Foundation*, BIOBRICKS.ORG, <http://biobricks.org/about-foundation/> (last visited Feb. 12, 2012).

⁷⁹ *Compare The BioBrick Contributor Agreement*, BIOBRICKS.ORG, <http://biobricks.org/wp-content/themes/bbf/bpa-sample.php> (last visited Feb. 12, 2012) with *Open Source Definition*, *supra* note 64.

⁸⁰ *Frequently Asked Questions*, BIOBRICKS.ORG, <http://biobricks.org/bpa/faq/> (last visited Feb. 11, 2012).

There are two distinct types of contract—one for the “Contributor” and one for the “User.”⁸¹ The Contributor is the person making the biological part available, while the User is the person using the part that the contributor provided.⁸² The Contributor contract states that a Contributor of a BioBricks part makes “an irrevocable promise not to assert any existing or future intellectual property rights over the something against the other party to the contract.”⁸³ Furthermore, the Contributor of a BioBricks part must disclose the existence of any intellectual property rights to the part held either by the Contributor or by a third party.⁸⁴ The User contract states that a User promises to “provide attribution to the contributor, where requested, and to respect biological safety practices and applicable laws.”⁸⁵

Some commentators have noted that the BioBricks Public Agreement sets forth more than the mere terms of a license intended to prevent disputes over ownership rights.⁸⁶ Rather, the terms of the BioBrick Agreement are “an initial effort to draft a legal constitution to guide the beneficial development of the field of synthetic biology.”⁸⁷

Importantly, the BioBricks Public Agreement does not include some provisions included in the OSI terms of distribution.⁸⁸ For example, the BioBricks Public Agreement does not contain any provision requiring a grantback of any derived works.⁸⁹ As discussed in the following section, the absence of some OSI terms of distribution will create significant challenges to maintaining an open-source synthetic biology movement.

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *The BioBrick Contributor Agreement*, BIOBRICKS.ORG, <http://biobricks.org/wp-content/themes/bbf/bpa-sample.php> (last visited Feb. 12, 2012) (section 4, Intellectual Property Rights).

⁸⁵ *Frequently asked Questions*, *supra* note 80; *The BioBrick User Agreement*, BIOBRICKS.ORG, <http://biobricks.org/bpa/users/agreement/> (last visited Feb. 12, 2012).

⁸⁶ Andrew Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J. L. SCI. & TECH. 629, 663 (2010).

⁸⁷ *Id.*

⁸⁸ *See Frequently asked Questions*, *supra* note 80.

⁸⁹ *Id.*

C. Challenges Maintaining the BioBricks Commons

There are several significant threats to the openness of the BioBrick commons. Three of these challenges will be discussed in this section specifically. The first challenge is *derivation*: getting contributors to donate derived work back to the BioBricks Foundation and not assert any intellectual property rights. The second challenge is *motivation*: incentivizing individuals or entities that currently hold patent rights of biological parts to donate them to the BioBricks Foundation in the first place. The third challenge is the absence of an *end product*: the open source synthetic biology community will not be able to realize the potential of novel medically relevant inventions on its own. The first two challenges stem from the terms of the BioBricks Public Agreement, while the third challenge is inherent in biomedically relevant research. Each challenge will be considered in turn.

i. Derivation

One of the goals of the BioBricks Foundation open-source community is to foster the creation of novel biological parts by derivation from the parts currently found in the registry.⁹⁰ But the absence of terms in the BioBricks Public Agreement that require all derived works to be donated back to the BioBricks Foundation creates a challenge. Unless they are the inventor of the biological part, a User would be barred from asserting any intellectual property rights over any individual biological part once contributed to the BioBricks Foundation.⁹¹ But there is nothing stopping a user from asserting intellectual property rights over a different biological part that is *derived from* BioBrick parts. In other words, if a person has signed the BioBricks User Agreement and, in using the BioBrick parts, creates a new part with a novel function, there is

⁹⁰ See *About the BioBricks Foundation*, *supra* note 78.

⁹¹ 35 U.S.C. § 102 (2006).

nothing stopping that person from patenting that novel part and asserting intellectual property rights over it. In fact, the User Agreement specifically states that there is no requirement to give any novel materials or applications back to the foundation.⁹² The BioBricks Foundation makes perfectly clear that “[n]ovel materials and applications produced using BPA-contributed parts may be considered for protection via conventional property rights.”⁹³ As a result, the BioBricks User Agreement is fundamentally different from the traditional open source agreement, which requires any derived works to be licensed back under the same terms as the original.⁹⁴ Without a reciprocal licensing mechanism in place to ensure that novel biological parts will continue to be derived from past work of users, maintaining a cycle of innovation by participants in the synthetic biology commons may be challenging.

ii. Motivation

A second problem, arguably equally as important as the first, is that there is no clear reason for a person with intellectual property rights over a part to surrender those rights and donate the part to the BioBricks Foundation. Arguably, the only motivation is to make a philanthropic gesture. Professor Andrew Torrance has noted that “it is not obvious what incentives contributors would have to contribute their BioBricks, especially if they must relinquish any intellectual property rights they may have in order to do so.”⁹⁵

iii. End Product

⁹² *Frequently Asked Questions*, supra note 80.

⁹³ *Id.*

⁹⁴ *Compare The BioBrick Contributor Agreement*, BIOBRICKS.ORG, <http://biobricks.org/wp-content/themes/bbf/bpa-sample.php> (last visited Feb. 12, 2012) with *Open Source Definition*, supra note 64.

⁹⁵ Torrance, supra note 86, at 660.

There is a third problem that is unique to synthetic biology as applied to the field of medicine—there is no immediately usable end product.⁹⁶ Other open-source movements, such as the open source software movement, were wildly successful partly due to the fact that a working product resulted from the aggregate work of many individuals. For example, the Linux operating system, developed over many years by thousands of people, is downloaded and used by anyone in the world after all the effort has been put forth to make it.⁹⁷ That is not always the case in the world of biotechnology.⁹⁸ If members of the BioBricks Foundation were to engineer a microbe to be a medical therapy, the end product could not be immediately used because introduction of the product requires lengthy, and extremely costly, clinical trials as a drug, biologic, or medical device.⁹⁹ It is likely that an entire community of BioBricks members would not have the knowledge or resources available to undergo this task.

Thus, there are several problems to overcome in establishing a viable open source synthetic biology movement. The first is getting people/corporations to make their derived works, which may be very valuable, available for further use by the public free of charge. The second is getting people/corporations with intellectual property rights to contribute parts. The third, in the context of designing a medical therapy, is getting a synthetic biology product through clinical trial so that it will actually be used to benefit the world.

The first two problems have been addressed in the context of other open-source movements involving emerging technologies under the threat of patents stifling progress.¹⁰⁰ In

⁹⁶ See Bernard Munos, *Can Open-source R&D Reinvigorate Drug Research?*, 5 NATURE REVIEWS DRUG DISCOVERY 723, 724 (2006) (“There are, however, significant barriers to the deployment of open-source approaches to drug R&D. One is economic. All it takes to write open-source software is a laptop and an internet connection. With drug research, someone must pay for laboratory expenses and clinical trials.”).

⁹⁷ See *Download Linux Free*, <http://downloadlinuxfree.com/> (last visited Apr. 6, 2012).

⁹⁸ See Munos, *supra* note 96.

⁹⁹ *Id.*

¹⁰⁰ See *infra* Part IV.

the context of those specific technologies, several different strategies have been devised to maintain openness. Parts IV and V will address three strategies that have been applied to other technologies that can potentially be applied to maintaining open source synthetic biology. Each of the following strategies has been evaluated previously in the context of a specific technology and each has been successful in maintaining some degree of openness.¹⁰¹ Part IV will introduce these previously proposed strategies. Part V will answer the question of whether any of the proposed strategies would be applicable to a synthetic biology commons, and if so, whether it would be successful. The three strategies to be evaluated are the Copyright Open-Source approach, the HapMap License approach, and the BIOS patent approach.

IV. Previously Proposed Open Source Strategies

A. Copyright Open-Source Approach

Currently, copyright protection for sequences of DNA is not available.¹⁰² But if sequences of DNA *could* be protected under Copyright Law, then it would be relatively straightforward to implement open-source synthetic biology in an analogous fashion to open-source software.¹⁰³ A license to use the DNA “work” would include provisions that require the user to give back to the commons any derivative works.¹⁰⁴ The General Public License (GPL)¹⁰⁵

¹⁰¹ *Id.*

¹⁰² See Micheal A. Epstein, MODERN INTELLECTUAL PROPERTY, Ch. 11, II, C 458–59 (2d ed. 1992) (no cases or statutes have addressed the applicability of Copyright to sequences of DNA).

¹⁰³ See Torrance, *supra* note 86; Christopher M. Holman, *Copyright For Engineered DNA: An Idea Whose Time Has Come?*, 113 W.VA. L. REV. 699 (2011).

¹⁰⁴ *GNU General Public License, Version 3*, OPENSOURCE.ORG, <http://www.opensource.org/licenses/gpl-3.0.html> (last visited Feb. 11, 2012) (“Each time you convey a covered work, the recipient automatically receives a license from the original licensors, to run, modify and propagate that work, subject to this License.”).

¹⁰⁵ *Id.*

that has been commonly used in open source software could be easily adapted to cover DNA¹⁰⁶ and would have the same open source effect—novel sequences of DNA or novel combinations of established sequences that have been derived from previous work covered by the GPL would remain available to the public.

Several commentators have suggested that it is feasible for sequences of DNA to be covered by copyright law.¹⁰⁷ Some have even suggested that this approach could be used to establish open source synthetic biology.¹⁰⁸ These scholars have reasoned that DNA sequences are very similar to computer software code because both involve a set of instructions that are read, then executed, and any unique issues that might arise in the context of synthetic biology could be absorbed with a relatively small incremental change to Copyright Law.¹⁰⁹

For example, Dr. Christopher Holman makes the case that engineered DNA should be protected by Copyright Law.¹¹⁰ He argues that “the major doctrinal leap occurred thirty years ago when copyright protection was recognized for computer programs. In view of the close analogy between software and engineered DNA, the further extension to encompass engineered genetic sequences is a relatively modest incremental expansion.”¹¹¹ Dr. Holman argues that engineered sequences of DNA and computer code both are essentially sets of instructions that are read and executed by hardware.¹¹² For computer code, the hardware is the group of computer components itself; for DNA sequences, the hardware is the group of proteins, carbohydrates, and

¹⁰⁶ Holman, *supra* note 103 (There is a strong similarity between computers executing software code and cells expressing genes, which suggests that copyright could be easily applied to engineered DNA sequences).

¹⁰⁷ See Holman, *supra* note 103; Torrance, *supra* note 86.

¹⁰⁸ Holman, *supra* note 103; Torrance, *supra* note 86.

¹⁰⁹ *Id.*

¹¹⁰ See Holman, *supra* note 103.

¹¹¹ *Id.* at 703.

¹¹² *Id.*

fatty acids that make up a living cell.¹¹³ Further bolstering the Copyright argument, advances in biotechnology have made possible a certain level of creativity in generating DNA sequences.¹¹⁴ This is important because the Supreme Court, in *Feist Publications, Inc. v. Rural Telephone Service Co. Inc.*,¹¹⁵ established a minimum threshold for a work to be covered by Copyright Law—the work must contain “a modicum of creativity.”¹¹⁶ This is a relatively low threshold that could be easily met even with the current state of synthetic biology because the current state of the technology allows for the creation of DNA sequences that are different—at least modestly—from what exists in nature.¹¹⁷ Additionally, the Supreme Court has consistently interpreted the Copyright Clause of the constitution broadly.¹¹⁸ The term “writing” has not been taken literally—photographs, art, motion pictures, and sounds have all been considered “writings.”¹¹⁹ Thus, there is good reason to believe that a molecule of DNA could be considered a “writing” and therefore could receive copyright protection.

Andrew Torrance makes a similar argument, but suggests that instead of only thinking about DNA sequences as being *analogous* to computer software, DNA might even be thought of as an *actual form* of computer software.¹²⁰ This is especially true in the field of synthetic biology, where in the future a heightened degree of programmability will allow for a potentially limitless amount of creativity.¹²¹ This is seemingly equivalent to the freedom of a computer programmer to create any form of program, constrained only by the computer language and

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Feist Publ’n, Inc. v. Rural Tel. Serv. Co., Inc.*, 499 U.S. 340 (1991).

¹¹⁶ *Id.*

¹¹⁷ *See generally* Ruder, Lu & Collins, *supra* note 38.

¹¹⁸ *See* Holman, *supra* note 103.

¹¹⁹ *See* *Kalem Co. v. Harper Bros.*, 222 U.S. 55 (1911); *Bleistein v. Donaldson Lithographing Co.*, 188 U.S. 239 (1903); *Goldstein v. Cal.*, 412 U.S. 546 (1973); *Burrow-Giles Lithographic Co. v. Sarony*, 111 U.S. 53 (1884).

¹²⁰ Torrance *supra* note 86, at 647 (“Rather than portray DNA sequences as analogous to computer software, a synthetic biologist might consider DNA sequences actually to be a form of computer software.”).

¹²¹ *See generally* Endy, *supra* note 28.

hardware itself. Indeed, Torrance even notes that one of the “goals of synthetic biology is to engineer cells and genes to become ever more like computers and computer software.”¹²² If this approach is assumed, then DNA is already covered by Copyright and no adaptation of law need be made at all in order to protect sequences of DNA.

B. HapMap Licensing Approach

Some open-source movements use a contract-based license to create an information commons in the realm of biotechnology and have been relatively successful.¹²³ One in particular, the International HapMap Project, was a joint public-private venture to map genetic variation among the world’s human population.¹²⁴ The stated goal of the HapMap project was to “help researchers find genes associated with human disease and response to pharmaceuticals.”¹²⁵ The HapMap Project originally created a data access policy that was meant to “avoid the filing of intellectual property claims that would impede other users access to the data.”¹²⁶ Due to the success of open distribution, in 2004, approximately two years after the HapMap project had started distributing haplotype data, the HapMap Consortium decided that its data access policy was no longer required because enough data on human genetic variation was published that any patents derived from HapMap data would be considered obvious.¹²⁷ Since then, all access to

¹²² *Id.*

¹²³ *The International HapMap Project*, About the International HapMap Project, <http://hapmap.ncbi.nlm.nih.gov/abouthapmap.html> (last visited Apr. 6, 2012).

¹²⁴ *Id.*

¹²⁵ *The International HapMap Project*, News, <http://hapmap.ncbi.nlm.nih.gov/> (last visited Feb. 11, 2012).

¹²⁶ 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, 1483 (2007).

¹²⁷ See *NIH News Release*, GENOME.GOV, <http://www.genome.gov/12514423> (last visited Feb. 12, 2012); Gitter *supra* note 89, at 1485; 35 U.S.C. § 103 (2006).

HapMap haplotype data is freely accessible to anyone without having to sign a license agreement.¹²⁸

The data-access policy that the HapMap Consortium formerly used included a licensing agreement that a user had to sign before gaining access to haplotype data.¹²⁹ This mandatory licensing agreement stated that “you will have to agree to a single condition—that you will not restrict further use of the individual genotypes, i.e. take any action that would in any way restrict the access of others to the data produced by the Project.”¹³⁰ The licensing agreement also prohibited distribution of data from the HapMap project to parties that had not accepted the terms of the license.¹³¹ This provision addressed the possibility that a party who signed the license could simply give the haplotype data to a third party who had not signed it and was not bound by its terms.

C. The BiOS patent approach

Another past strategy to establish and maintain openness is a patent-based approach, which the Biological Innovation for Open Society (BiOS) utilized.¹³² The BiOS initiative was created “in response to inequities in food security, nutrition, health, natural resource management and energy.”¹³³ BiOS currently holds the intellectual property rights to several technologies relevant to food production.¹³⁴ For example, BiOS holds patents on several plant technologies,

¹²⁸ *Data Access Policy for the International HapMap Project*, Registration for Access, <http://hapmap.ncbi.nlm.nih.gov/cgi-perl/registration> (last visited Feb. 11, 2012).

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² BiOS is an initiative of the Center for the Application of Molecular Biology to International Agriculture (CAMBIA). See CAMBIA.ORG, <http://www.cambia.org/daisy/cambia/home.html> (last visited, Feb. 12, 2012).

¹³³ *BiOS*, BIOS.NET, <http://www.bios.net/daisy/bios/home.html> (last visited Feb. 11, 2012).

¹³⁴ *IP Portfolio Licensable From Cambia*, CAMBIA.ORG, http://www.cambia.org/daisy/cambialabs/ip_portfolio.html (last visited Feb. 11, 2012).

including plant-gene transfer methods, generation of plant-gene fusions, and methods for genotyping genetically engineered plants.¹³⁵ Because BIOS holds the patent rights associated with those technologies, it can make those technologies freely available to anyone who wishes to use them if they agree to the terms of the BIOS license.¹³⁶ The mandatory license requires users to “grant back any improvements in the core technology and to make such improvements freely available to all others on the same terms that BIOS provided for the original core technology.”¹³⁷

Some academics, such as Professor Robin Feldman, suggest that this grantback requirement may implicate patent misuse.¹³⁸ Patent misuse occurs when the patent holder attempts to expand the physical or temporal scope of a patent monopoly beyond what was originally granted in the patent.¹³⁹ “To the extent that a patent holder uses its rights to restrict the disposition of inventions not covered by the grant, the patent holder may be engaging in behavior that extends the scope of the patent grant and thereby may be subject to a claim of misuse.”¹⁴⁰ But by Professor Feldman’s reasoning, it is highly unlikely that BIOS would actually find itself in court under a theory of patent misuse because the BIOS grantback requirement is not inconsistent with patent policy and any anti-competitive effects are outweighed by the pro-competitive benefits.¹⁴¹

¹³⁵ *Id.*

¹³⁶ Cambia is in the process of abandoning its licensing agreement and material transfer agreement requirements in order to maximize the public use of its technology. But the BIOS strategy for maintaining openness is still relevant to the discussion because the strategy is still available for any person or entity holding patent rights in a technology. *See IP Portfolio Licensable From Cambia*, CAMBIA.ORG, http://www.cambia.org/daisy/cambialabs/ip_portfolio.html (last visited Feb. 11, 2012).

¹³⁷ Robin Feldman, *The Open Source Biotechnology Movement: Is it Patent Misuse?*, 6 MINN. J.L. SCI. & TECH. 117, 128 (2004).

¹³⁸ *Id.*

¹³⁹ *Id.* at 118–19.

¹⁴⁰ *Id.* at 141–42.

¹⁴¹ *See Id.* (Although outside the scope of this comment, Professor Feldman applies open-source grantback requirements to a two part test. The first part is whether the grantback requirements of the patent holder are inconsistent with patent policy. The second part is whether the grantback requirement fails the anti-trust rule of

V. Application of Past Strategies to Synthetic Biology

In light of the previous open-source strategies described in Part IV, the question is whether any of the copyright, license, or patent based approaches to maintaining openness would work in the context of synthetic biology. The following section applies these previous strategies to synthetic biology and assesses whether any of them can be used to maintain an open source synthetic biology movement. Application of these strategies to the technology of synthetic biology reveals that none of them are ideally suited to maintaining openness. The copyright approach and patent based approach are especially unlikely to be useful because of recent federal circuit decisions and prohibitive expense, respectively. While the license based approach can be applied to synthetic biology, it has several flaws that must be overcome in order to sustain an open source synthetic biology movement.

A. Copyright Availability For Open Source Synthetic Biology

The Copyright approach to open-source synthetic biology is not without problems because the applicability of copyright to sequences of DNA is untested. While various scholars have made several compelling arguments that DNA sequences *should* be covered by Copyright Law, there is currently no indication that the U.S. Copyright Office or Congress would approve the use of Copyright Law to protect DNA sequences.¹⁴² Also, Andrew Torrance, Sapna Kumar and Arti Rai have pointed out that the Copyright approach may not work for DNA sequences that

reason. Professor Feldman argues that open source biotechnology movement should not be considered patent misuse because the grantback requirement does not fail either test).

¹⁴² See Holman, *supra* note 103, at 702.

already exist in nature.¹⁴³ Indeed, Copyright is intended to prevent verbatim copying of a writing, whether it be in the form of computer software or DNA sequence.¹⁴⁴ Thus, no naturally-occurring sequences of DNA could be protected under a Copyright.¹⁴⁵ While designing novel DNA sequences that do not exist in nature may become commonplace in the future with synthetic biology, the current state of the technology largely involves previously existing genetic code.¹⁴⁶ For example, the vast majority of BioBrick parts made available in the registry are sequences of DNA taken directly from naturally-occurring organisms.¹⁴⁷

The Federal Circuit's view on intellectual property rights of DNA poses another high hurdle for DNA Copyright protection.¹⁴⁸ While there is no *direct* indication that the Federal Circuit would approve or disapprove the use of Copyright to protect sequences of DNA, there is some *indirect* indication that it would not be receptive to Copyright protection for sequences of DNA, even if the sequences were completely novel.¹⁴⁹ The Association for Molecular Pathology et al. v. United States Patent and Trademark Office et al. (Myriad gene patent case) offers some insight into how the Federal Circuit views intellectual property rights surrounding sequences of DNA.¹⁵⁰ While patents and copyrights are distinct bodies of intellectual property law, the court's

¹⁴³ See Torrance, *supra* note 86; see Kumar & Rai, *supra* note 57.

¹⁴⁴ 17 U.S.C. § 101 (“Copies’ are material objects . . . in which a work is fixed by any method now known or later developed”).

¹⁴⁵ 17 U.S.C. § 102 (b) (“In no case does copyright . . . extend to any . . . *discovery*, regardless of the form in which it is described, explained, illustrated, or embodied”) (emphasis added).

¹⁴⁶ See e.g., *Promoters/Catalog/Constitutive*, PARTSREGISTRY.ORG, <http://partsregistry.org/Promoters/Catalog/Constitutive> (last visited Feb. 12, 2012) (In this example category, all of the BioBricks constitutively active promoter sequences have been cloned from a naturally occurring organism; each sequence has a prokaryotic, eukaryotic, or phage origin).

¹⁴⁷ *Id.*

¹⁴⁸ See *Ass’n for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al.*, 702 F.Supp.2d 181 (S.D.N.Y. 2010).

¹⁴⁹ See *id.*; *Ass’n of Molecular Pathology et al. v. U.S. Patent and Trademark Office et al.*, 653 F.3d 1329 (Fed. Cir. 2011), vacated and remanded in March 2012.

¹⁵⁰ *Id.*

reasoning in the gene patent cases may be an indication of future unwillingness to allow Copyright protection for DNA.¹⁵¹

On July 29, 2011, a three-Judge panel in the Federal Circuit handed down three separate opinions in the controversial Myriad gene patent case.¹⁵² The original decision on appeal, authored by Judge Sweet from the Southern District of New York, held that a composition of isolated genomic DNA was not patentable subject matter.¹⁵³ Judge Sweet seized the idea that DNA is a carrier of *information* and that this property gives it utility.¹⁵⁴ Any isolated DNA containing the same sequence information of native DNA is therefore a product of nature and unpatentable.¹⁵⁵ Two out of the three judges on the Federal Circuit panel, completely rejected Judge Sweet's reasoning.¹⁵⁶ Judge Lourie held that focusing on the "information content contained in . . . DNA's nucleotide sequence" ignores the distinctive characteristics that isolated DNA molecules have when compared to what exists in nature.¹⁵⁷ Judge Lourie further stated that when determining patent eligibility of DNA, the "informational content is irrelevant."¹⁵⁸ Judge Moore concurred with Judge Lourie on the issue of patent eligibility of isolated genomic DNA sequences, but wrote separately to emphasize the differences in utility of isolated DNA when compared to native DNA.¹⁵⁹

¹⁵¹ *Id.*

¹⁵² Ass'n of Molecular Pathology et al. v. U.S. Patent and Trademark Office et al., 653 F.3d 1329 (Fed. Cir. 2011).

¹⁵³ Ass'n for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al., 702 F.Supp.2d 181 (S.D.N.Y. 2010).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ See Ass'n for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al., 653 F.3d 1329 (Fed. Cir. 2011) (majority opinion) (Moore, K., concurring).

¹⁵⁷ *Id.* at 1353.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 1365 (There were two separate issues with respect to patent eligibility of DNA sequences. One issue involved the patentability of cDNA sequences, which do not exist in nature and are derived from mRNA. All three judges in the Federal circuit agreed that this particular type of DNA is patent eligible. The other issue involved patentability of isolated genomic DNA. Isolated genomic sequences of DNA do exist in nature, but in the context of

If the majority of the Federal Circuit panel had agreed with Judge Sweet and emphasized the *information* carrying qualities of DNA, a parallel argument could be made that, while not patentable, sequences of DNA could be protected by copyright law. If the informational aspect of a molecule of DNA was emphasized, then one could reasonably argue that the genetic information is simply read and executed by other cellular machinery in an analogous fashion to a computer reading and executing software instructions.¹⁶⁰ Thus, if courts emphasize the informational aspect of DNA, then there would exist some judicial reasoning in support of the conclusions of Hollman and Torrance that Copyright should be applicable to sequences of DNA, much like Copyright is applicable to computer software.¹⁶¹

Since the majority of panel judges rejected viewing DNA as, first and foremost, a carrier of information, the arguments for the copyright protection of DNA sequences would not find support in the reasoning of the Federal Circuit. Furthermore, with the Federal Circuit's decision in the Myriad gene patent case, patents are clearly available for protection of sequences of DNA.¹⁶² As Kumar and Rai have noted, "courts and Congress might be reluctant to layer on an entirely new kind of property right, for fear that such rights would hurt rather than help innovation."¹⁶³ Thus, despite the sound arguments for why DNA *should* be protected under copyright law, it is unlikely that the Federal Circuit *would* actually support its use in that context.

The intellectual property rights available to sequences of DNA may change in the future. The Ass'n for Molecular Pathology et al. appealed the Federal Circuit's Myriad gene patent case decision to the Supreme Court, which remanded the case to the Federal Circuit for consideration

a whole chromosome. The patentability of isolated genomic DNA was the subject of dispute among the three judge panel in the Federal circuit).

¹⁶⁰ See Holman, *supra* note 103; Torrance, *supra* note 86.

¹⁶¹ *Id.*

¹⁶² See Ass'n for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al., 653 F.3d 1329 (Fed. Cir. 2011) (majority opinion) (Moore, K., concurring).

¹⁶³ Kumar & Rai *supra* note 57, at 1764.

in light of the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories*.¹⁶⁴ If the Supreme Court eventually takes the case and upholds the Federal Circuit majority, then the applicability of copyright protection to sequences of DNA will remain unlikely. But if the Supreme Court were to agree with Judge Sweet, and emphasize the information-carrying properties of DNA sequences, it could effectively close the door on genomic DNA patents and open the door to genomic DNA copyrights.

B. Application of HapMap Strategy to the BioBrick Public Agreement

Application of a HapMap license approach to maintaining an open source synthetic biology movement is possible, but brings with it issues associated with third-parties not in privity of contract and issues of enforcement. The HapMap Licensing terms, which were relatively successful in establishing the open use of haplotype data, have some similarities to the current BioBricks Public Agreement.¹⁶⁵ Both agreements contain terms that prohibit placing restrictions on the information/part that has been made available.¹⁶⁶ Importantly, this strategy does not require any intellectual property right to bind the signing party to the terms of the license.¹⁶⁷ Kumar and Rai note that “this contractual alternative does not require an underlying property right. Instead, the contract simply imposes conditions as part of the price of access.”¹⁶⁸ Furthermore, the online nature of a license-based strategy requires that the agreed upon web-based contract be enforceable. Donna Gitter has noted that “courts generally enforce clickwrap

¹⁶⁴ As of the date of this writing, the Supreme Court has sent the *Myriad* gene patent case back down to the lower courts to be re-evaluated in light of the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ____ (2012). At this time, it is not at all clear whether the Supreme Court will hear the *Myriad* gene patent case in the future.

¹⁶⁵ Compare *The BioBrick Contributor Agreement*, *supra* note 94 with *Data Access Policy for the International HapMap Project*, *supra* note 128.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ Kumar & Rai *supra* note 57, at 1766.

agreements provided the licensee ‘receive[s] notice of the license terms before buying or using’ . . . ‘and has the ability to return . . . if he does not agree with the terms . . . ’¹⁶⁹ Since the HapMap user agreement was deemed to fulfilled these threshold requirements for enforceability, the similar click-wrap nature of the BioBricks agreement would likely fulfill these threshold requirements as well. There are, however, several issues that still must be overcome.

i. Third-Party Problems

Third parties not in privity of contract who gain access to BioBricks parts, however, will create problems that must be overcome. Commentators have pointed out that a licensing agreement would not prevent third parties, who have gained access without signing, from violating its terms.¹⁷⁰ Gitter points out that the HapMap license “does not bind third parties who obtain and use HapMap data without downloading it from the HapMap website and who therefore are not in privity of contract . . . ”¹⁷¹ A similar problem exists in the case of the BioBricks Public Agreement; any third party that obtains a BioBrick part without agreeing to the license would not be bound by its terms.¹⁷² The HapMap approach to overcoming this problem was to include terms in the user agreement that specifically prohibited dissemination of HapMap data to parties that have not signed an agreement.¹⁷³ Kumar and Rai suggest that this indicates one of the difficulties when using contract law to maintain openness: “the comparative weakness of the contractual restraints paradoxically requires extremely broad restrictions on dissemination.”¹⁷⁴ A similar contradiction would exist in the context of the synthetic biology

¹⁶⁹ Gitter *supra* note 126, at 1487.

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 1488.

¹⁷² Compare *The BioBrick Contributor Agreement*, *supra* note 94 with *Data Access Policy for the International HapMap Project*, *supra* note 128.

¹⁷³ *Data Access Policy for the International HapMap Project*, *supra* note 128.

¹⁷⁴ Kumar & Rai, *supra* note 57, at 1764.

commons: the openness of the BioBricks parts could only be protected from third parties by severely restricting the openness of the BioBricks parts.

The BioBricks Foundation has not, however, implemented this type of third-party restriction.¹⁷⁵ In contrast, the BioBricks Foundation's ethos of openness suggests that it would actually want to *encourage* the free distribution of BioBricks parts to third parties in hopes of a third-party eventually making a donation back to the foundation.¹⁷⁶ Thus, any third-party issues that existed in the context of the HapMap project will likely be amplified greatly in the context of the BioBrick Foundation, due to the absence of dissemination restrictions.

ii. Enforcement Problems

In addition to the problems associated with third parties violating the terms of a license, there may also be enforcement problems even with parties who *have agreed* to the license terms. For example, a party may agree to a license that relinquishes any intellectual property rights, but that party may later ignore the provision and file for a patent anyway. Under this circumstance, there is no reason to believe that the patent would be void. As Professor David Opderbeck has noted, “[n]othing in the Patent Act would suggest that a patent could be invalidated because some of the underlying data was derived from a database in violation of the database’s terms of use. Thus it is unlikely that the [license] provides any meaningful remedy once a patent has been filed.”¹⁷⁷ In terms of the BioBrick Public Agreement, an individual could fail to disclose the existence of a pending patent on a biological part, but the resulting patent would not be invalidated due to this violation.¹⁷⁸ Thus, users may disregard the terms of the BioBricks Public

¹⁷⁵ *Frequently Asked Questions*, *supra* note 80.

¹⁷⁶ *Id.*

¹⁷⁷ Opderbeck, *supra* note 34, at 199.

¹⁷⁸ *See id.*

Agreement, which are meant to maintain openness, without any real recourse for the BioBricks Foundation.¹⁷⁹

There are further issues that arise if the Foundation decided to enforce the terms of the BioBricks Agreement in court. Gitter notes that bringing suit against all parties who violate the user agreement would “create a significant financial and administrative strain upon the nonprofit research group, which must focus its efforts on pursuing research as opposed to enforcing its data access policy.”¹⁸⁰ This certainly applies to the BioBrick Foundation, which is also a non-profit organization and has limited financial resources. Additionally, the area of biotechnology is very much an international enterprise, and there may be no remedy against people who violate the terms of the BioBricks Agreement in other countries.¹⁸¹ As Gitter states, “[i]f the user happens to be located in a nation that does not enforce clickwrap licenses, then that user might not face legal liability for violating the . . . license.”¹⁸²

C. Application of BIOS Approach to BioBricks

There are several problems with attempting to maintain the synthetic biology commons using a patent-based strategy. First, for this strategy to work, BioBricks would have to hold either a few broad foundational patents or a patent on each individual part in the collection. Both of these options pose problems.

¹⁷⁹ *Id.*

¹⁸⁰ Gitter *supra* note 89, at 1489.

¹⁸¹ *Id.*

¹⁸² *Id.* at 1491.

Unlike the BiOS Initiative, currently the BioBricks Foundation does not hold the patent rights to any broad foundational patents.¹⁸³ While a few broad foundational patents might be successfully used to maintain a commons, the difficulty with this approach would be to “identify an area of inventive territory that was quite broad but nonetheless not suggested either by prior broad patents or by information already in the public domain.”¹⁸⁴ Considering the existence of several issued broad foundational patents, it is not likely that the BioBricks Foundation would be successful if it were to proceed with this approach.

The alternative is to obtain a very narrow patent on each BioBricks part currently in the registry. This strategy would not only require the BioBricks Foundation to patent each part for which it is the inventor, it would also require each individual “inventor” who donates his or her part to the Foundation to obtain a patent as well. This is not practically possible. Obtaining a patent on a sequence of DNA, or any other structure or method, could cost tens of thousands of dollars each.¹⁸⁵ The BioBrick registry currently holds thousands of BioBrick parts.¹⁸⁶ Thus, the aggregate cost of maintaining a synthetic biology commons by patenting each individual part would easily be in the tens of millions of dollars. This is a prohibitively large amount even for a large for-profit corporation and simply is not possible for the BioBrick Foundation.

¹⁸³ Several members of the BioBricks Board of Directors hold patents as individuals, but there is no indication that the Foundation itself holds any patents. *See e.g., Board of Directors*, BIOBRICKS.ORG, <http://biobricks.org/about-foundation/board-of-directors/> (Tom Knight, one of the founding members of BioBricks, holds over 30 patents).

¹⁸⁴ Kumar & Rai *supra* note 57, at 1765.

¹⁸⁵ *The Cost of Obtaining a Patent in the US*, IPWATCHDOG.COM, <http://www.ipwatchdog.com/2011/01/28/the-cost-of-obtaining-patent/id=14668/> (last visited Feb. 12, 2012) (Even the simplest technologies costs approximately \$5,000-7,000 in attorney’s fees to obtain a patent, while more complicated technologies can cost in excess of \$15,000).

¹⁸⁶ There is no official count of the available BioBricks parts, but by simply browsing the registry, it is clear that there are many thousands of parts. *Registry of Standard Biological Parts*, PARTSREGISTRY.ORG, http://partsregistry.org/Main_Page (last visited Apr. 6, 2012).

VI. A standard setting organization (SSO) strategy for establishing, maintaining, and using the end products of the synthetic biology commons

Part IV of this Comment introduced various strategies that have been used in the past for maintaining openness in different technological areas.¹⁸⁷ Part V then applied those strategies to the technology of synthetic biology, concluding that a copyright- or patent-based approach is not possible and a license approach is less than ideal.¹⁸⁸ Each of the previous strategies discussed to this point only address the problem of getting derived works of synthetic biology donated back to an open source community. The problem of motivating patent holders to donate biological parts in the first place and the problem of getting biomedical end products into the clinic have not been addressed. The following subsections lay out a novel strategy that may be able to tackle problems of maintaining openness while at the same time incentivizing donations and creating opportunities for realizing biomedical breakthroughs. This strategy involves establishing a synthetic biology standard setting organization (SSO).

A. Standard Setting Organizations (SSO)

An SSO, also known as standard setting consortia, can consist of “anything from a loose, unincorporated affiliation of companies, to an incorporated entity with offices, marketing, technical and administrative staff and a multi-million dollar budget.”¹⁸⁹ The goal of this type of organization is to set standards that are widely adopted throughout an industry in order to enable innovation of a business-service or product.¹⁹⁰ The importance of standard setting cannot be

¹⁸⁷ See *supra* Part IV.

¹⁸⁸ See *supra* Part V.

¹⁸⁹ Andrew Upgrove, *Forming a Successful Consortium*, THE ESSENTIAL GUIDE TO STANDARDS, <http://www.consortiuminfo.org/essentialguide/whatisansso.php> (last visited Feb. 12, 2012).

¹⁹⁰ *Id.*

overstated. Standards are found everywhere in our daily life. The classic example is an electrical plug and socket¹⁹¹—people in the United States can go to any store in the country and purchase any tool or device that requires power and be confident that they will be able to go home and the plug will fit. Both the plug on the device and the electrical socket in the home are guaranteed to work together because a standard has been adopted. Furthermore, “[o]rdinary products like printer cartridges and tires come in standardized sizes and specifications, which fosters choice and competition in the supply of replacement parts.”¹⁹² Thus, standards have the beneficial effects of promoting efficiency of innovation as well as competition in a marketplace.

Standards can be broadly classified into three groups: de facto standards, private standards, and government standards.¹⁹³ De facto standards arise naturally in a market place when users adopt a standard to the exclusion of any competition.¹⁹⁴ Government standards, in contrast, are promoted and enforced by a government entity—for example, the U.S. government selected a uniform standard for High Definition television in the 1990’s.¹⁹⁵ Finally, private standards are adopted voluntarily by members of an industry, usually after the formation of a private SSO.¹⁹⁶ Joining a private SSO is completely voluntary, “some flourish, while others enjoy only middling success, and some fail to gain traction at all.”¹⁹⁷

¹⁹¹ Multi-Standard Sockets, *The Digital Museum of Plugs and Sockets*, <http://fam-oud.nl/~plugsocket/MultiSockets.html> (last visited Feb. 12, 2012).

¹⁹² Edith Ramirez, *The Federal Trade Commission Workshop on Intellectual Property Rights in Standard Setting*, FTC.GOV, <http://www.ftc.gov/speeches/ramirez/110621ssowkshp.pdf> (2011).

¹⁹³ Mark A. Lemly, *Intellectual Property Rights and Standard Setting Organizations*, 90 CAL. L. REV. 1889, 1899–1901 (2002).

¹⁹⁴ *Id.*

¹⁹⁵ James B. Koback, Jr., *Standard Setting, IP and Antitrust*, Practising Law Institute Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series, PLI Order No. 8816 (June 2006).

¹⁹⁶ Lemly, *supra* note 193, at 1899–1901.

¹⁹⁷ Upprove, *supra* note 189.

At the core of an SSO is the establishment of policies to deal with intellectual property rights, namely patents.¹⁹⁸ To accomplish this, each SSO establishes a set of rules addressing the intellectual property rights of members who have joined.¹⁹⁹ Two particularly important issues covered in the SSO rules are “whether and when patent claims must be disclosed” and the reasonable and nondiscriminatory (“RAND”) terms by which a member will license patent rights to other members.²⁰⁰ The RAND terms of a private SSO could possibly be designed to address the problems of maintaining open-source synthetic biology.

B. A Standard Setting Organization Could Address the Problems of Maintaining Open Source Synthetic Biology

The establishment of a private standard setting organization might address the problem of incentivizing donation of patented biological parts by creating a medium through which the part could be used by an open source community while at the same time protecting the intellectual property rights of the donor. An SSO might address issues involved with using a license to get derivative biological parts donated back to an open source community. Finally, an SSO could foster collaboration between an open source synthetic biology community and private entities in order to introduce synthetic biology products into the clinic.

i. Motivating Donation of Biological Parts

An SSO could overcome the problem of motivation by generating future value of a patented biological part, while at the same time protecting the intellectual property rights of the donor. In some situations donation of parts might be made freely. There is evidence that entities

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

holding patent rights over certain technologies would be willing to allow an open source community to use those technologies free of charge. For example, IBM has pledged several hundred patents to the open source community in order to foster innovation.²⁰¹

IBM is committed to promoting innovation for the benefit of our customers and for the overall growth and advancement of the information technology field. IBM takes many actions to promote innovation. Today, we are announcing a new innovation initiative. We are pledging the free use of 500 of our U.S. patents, as well as all counterparts of these patents issued in other countries, in the development, distribution, and use of open source software. We believe that the open source community has been at the forefront of innovation and we are taking this action to encourage additional innovation for open platforms.²⁰²

IBM is likely willing to donate patents because those patents are more valuable being used by the masses of an open source community than languishing undeveloped by the company. Future value from the use of patented technology by a community can be generated by technological advances that IBM can later capitalize on. There is no reason to think that this perceived future value is limited to the context of software. It is entirely possible that biotechnology companies and universities, which hold patents on foundational technologies relevant to synthetic biology, would similarly value work done by the open source community of the BioBricks Foundation.

But getting patent holders to donate the presently valuable intellectual property rights to an open source community will be more challenging. This is despite the fact that an open-source community can also generate future value from technology patents no matter what the present value is.²⁰³ Patent holders may be hesitant to donate their biological parts to the BioBricks Foundation via the standard BioBricks Public Agreement because it would prevent enforcement of any rights against users. The terms of the Public Agreement create a risk for an entity that has

²⁰¹ IBM Statement of Non-assertion of Named Patents Against OSS,
<http://www.ibm.com/ibm/licensing/patents/pledgedpatents.pdf> (last visited Feb. 12, 2012).

²⁰² *Id.*

²⁰³ See Micheal Fauscette, *The Value of Open Source*, IDC Analyst Connection, available at http://www.redhat.com/f/pdf/IDC_749_CarveOutCosts.pdf (last visited Apr. 6, 2012).

invested large sums of money in obtaining a patent over valuable sequences of DNA because a competitor could theoretically sign its own BioBrick Public Agreement and then be able to infringe patent rights with impunity. By donating a valuable biological part to the BioBrick Foundation, a patent holder might inadvertently give up rights to a direct competitor.

This problem could possibly be overcome by a direct agreement between the BioBrick Foundation and a patent holder, in which it is agreed to allow the use of patented technology by members of the BioBrick Foundation, without actually signing the Contributor Agreement. This, however, leaves open the possibility that the patent holder could decide to assert intellectual property rights at a later date, stopping all future innovation with the part. No member of the BioBrick Foundation would want to invest time developing a technology only to be told to stop at some future date.

The establishment of a private standard setting organization would create a medium through which the patented biological part could be given to BioBrick members while at the same time protecting the intellectual property rights of the donor. The private SSO would include a unique provision to achieve this end. The SSO contract would contain an ex-ante RAND term that creates a *sliding scale* based on the non-profit or for-profit nature of the entity using the patented material. For the non-profit organization, the reasonable and nondiscriminatory license fee would be zero. For all other organizations joining the private-SSO, the license terms would follow the fair market value of the patent rights. Using RAND terms of this nature will motivate patent holders of biological parts to donate them to an open source community because future value will be generated on the part, and competitors would not have the opportunity to exploit a donation.

ii. An SSO Addresses Issues of Enforceability Involved with a Licensing Agreement

As discussed in Section V above, one of the problems with using a contract licensing approach to maintaining openness in the BioBricks Foundation is that the terms can be violated by a party without any real recourse.²⁰⁴ For example, a donor of a biological part could make a promise not to assert any patent rights over a donated part, but then later demand that the part not be used. To remedy this, donation of biological parts under the umbrella of an SSO would make it perfectly clear that the agreement is not simply an agreement among parties to use the patented material, but rather the *adoption of a standard part* in which time and money will be invested. This clear establishment that a standard is being adopted will bring with it several aspects of protection that exist in common law.

There is clear case law indicating that, when a patent holder induces another party to adopt a standard, the patent holder cannot arbitrarily enforce his or her rights.²⁰⁵ One legal theory is that of equitable estoppel. In *Stambler v. Diebold, Inc.*, the plaintiff allowed the American National Standards Institute (ANSI) to adopt a technology relating to ATM machines as the standard.²⁰⁶ The court held that there was evidence of “misleading conduct on the part of the plaintiff that may have led the defendant to conclude that plaintiff did not intend to enforce his patent” and further that the conduct was intentional.²⁰⁷ The court used a theory of estoppel to deny the plaintiff the right to enforce the patent.²⁰⁸ The court reasoned that the plaintiff had a duty to speak out rather than allow the industry to adopt the standard.²⁰⁹

²⁰⁴ *See supra* Part V.

²⁰⁵ *Stambler v. Diebold, Inc.*, 11 U.S.P.Q.2d 1709 (E.D.N.Y. 1988).

²⁰⁶ *Id.*

²⁰⁷ *Id.* at 1714.

²⁰⁸ *Id.*

²⁰⁹ *Id.*

Furthermore, the Federal Circuit Court of Appeals has articulated a three-part test to determine whether a party may use equitable estoppel to bar a patent infringement claim.²¹⁰ The court put forward three elements required to invoke equitable estoppel.²¹¹ First, the patent holder must lead the infringer, by misleading conduct, to reasonably infer that no property rights will be asserted.²¹² Types of misleading conduct include “specific statements, action, inaction, or silence where there was an obligation to speak.”²¹³ Second, the infringer must have relied on the misleading conduct of the patent holder.²¹⁴ Third, the infringer will be materially prejudiced by allowing proceedings to continue.²¹⁵

Applying this three-part test would most likely result in equitable estoppel in the context of a biological part donated to the BioBricks Foundation under an SSO. If a BioBricks part Contributor tried to revoke the license of a patent after donating a biological part, all the elements of equitable estoppel would be fulfilled. First, the BioBricks Foundation would have reasonably inferred that the Contributor did not enforce the patent because of the acceptance of the contributor’s donation. Second, BioBricks would have relied on that agreement by depositing the DNA part into the registry. Third, the BioBrick Foundation would be materially prejudiced by enforcement because the foundation would have to, at minimum, spend the time and money removing the DNA part from the database.

An alternative legal theory preventing the assertion of patent rights over an adopted standard is that of an implied license.²¹⁶ Under this theory, future use of the donated biological part would not be protected, but damages could not be awarded for use up to the point of

²¹⁰ A.C. Aukerman Co. v. R.L. Chaides Construction co., 960 F.2d 1020 (Fed. Cir. 1992).

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.*

²¹⁴ *Id.*

²¹⁵ Aukerman Co., 960 F.2d at 1028.

²¹⁶ AMP Inc. v. U.S., 389 F.2d 448 (Ct. Cl. 1968).

notice.²¹⁷ In *AMP Incorporated v. The United States*, AMP entered into a contract with the government to furnish “60 experimental models of [a] wire splicing tool.”²¹⁸ The contract granted the government “an irrevocable, non-exclusive, nontransferable and royalty-free” license to use the tool.²¹⁹ After AMP had shipped the items, it discovered that its patent on the tool had been infringing another company’s patent.²²⁰ AMP purchased the rights to the other companies patent and then tried to revoke the original license it granted the government.²²¹ The court held that an implied license existed between AMP and the government, even though the government would have been infringing the third party’s patent.²²² The court reasoned that a license cannot be negated if there is no change in the structure of the invention.²²³

iii. Enforcing SSO Terms and Bringing Synthetic Biology to the Clinic

In the context of a standard setting organization, a scenario is created where proprietary entities and open source communities would have an aligned interest in the standard that gets adopted. The patent holder benefits from an increased value of an adopted standard; the parties using the patented technology would benefit from enhanced ability to innovate and collaborate through use of the standard. This alignment of interest could significantly benefit the BioBricks Foundation because the financial resources of a for-profit corporation might be used to prevent any individual member of the SSO from “gaming” the system.²²⁴ For example, an SSO member that promotes the use of a patented technology, but later tries to enforce patent rights on

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *AMP Inc.*, 389 F.2d at 448.

²²² *Id.*

²²³ *Id.*

²²⁴ *See Lemly, supra* note 193.

unreasonable terms, could be sued under one of the legal theories described above.²²⁵ Unfortunately, this would require financial resources that the BioBick Foundation does not have on its own. If, however, the interests of the other SSO members were aligned with that of the BioBrick Foundation, then a party with money to spend could be present, and would protect the interest of the BioBrick Foundation incidentally with its own self-interest. Thus, the legal recourse existing, but practically not possible to use, becomes available to the BioBrick Foundation in the context of an SSO.

Also, the aligned interests of the BioBrick Foundation with the for-profit members of the SSO make it possible to address a problem to establishing a synthetic biology commons that no other previously proposed strategy could—that is, get finished, medically relevant, products of BioBrick members out of the lab and into the clinic. For-profit biotechnology companies have the resources and expertise available to undergo the arduous process of a clinical trial. Also, since clinical trials last many years, the single entity of a corporation could stay focused on seeing the process through, without burdening any individual person. These are things that a synthetic biology commons could not achieve by its very nature, with many individuals investing little time and money and producing something big with their aggregate work. Thus, with the alignment of interests, the novel biological parts made by BioBrick members could be used freely by all for-profit members of the SSO. These novel biological parts could then be used to derive therapies, which can be patented, incentivizing investment into clinical trials. To keep the cycle of innovation going, the for-profit patented technologies could be adopted as standards and used further by BioBricks members under the same SSO terms.

²²⁵ See *A.C. Aukerman Co. v. R.L. Chaides Construction co.*, 960 F.2d 1020 (Fed. Cir. 1992); *AMP Inc. v. U.S.*, 389 F.2d 448 (Ct. Cl. 1968).

Conclusion

The emerging technology of synthetic biology promises to have a huge impact on industry and medicine.²²⁶ With that in mind, efforts should be made to promote the development of the technology in a way that maximizes the speed of innovation. In the world of biotechnology, where patents dominate,²²⁷ an open source approach to synthetic biology may be a good way to drive the technology forward and avoid potential stifling effects of intellectual property rights. This Comment has reviewed some problems associated with an open-source approach to synthetic biology and various strategies used in the context of other technologies for maintaining openness. This Comment argues that a patent or copyright approach for maintaining openness is not possible and that a license approach is less than ideal. This Comment proposes a novel SSO approach that could not only maintain openness, but also motivate donation of synthetic biology parts and help bring biomedical advances closer to clinical trials. The stated goal of the BioBrick Foundation is to “accelerate the pace of innovation, collapse development timelines and speed time-to-market of inventive synthetic biology-based solutions.”²²⁸ Private standard setting organizations have achieved these same ends with various other technologies.²²⁹ Thus, even though the BioBrick Foundation strategy for advancing synthetic biology involves largely open source principles, the goals of the Foundation may be better advanced by the establishment of a formal private standard setting organization. In a world where sequences of DNA are deemed patentable subject matter and intellectual property rights over foundational

²²⁶ Brent Erickson et al., *Synthetic Biology: Regulating Industry Uses of New Biotechnologies*, 333 SCIENCE 1254 (2011).

²²⁷ Sam Kean, *The Human Genome (Patent) Project*, 331 SCIENCE 530, 531 (2011).

²²⁸ *About the BioBricks Foundation*, *supra* note 63.

²²⁹ Upprove, *supra* note 189.

technologies threaten to stifle progress, creative thinking is necessary in order to advance synthetic biology, and unlock the vast potential it has to benefit the world.