

OPEN SOURCE SYNTHETIC BIOLOGY: PROBLEMS AND SOLUTIONS

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I. INTRODUCTION

In recent years, the scientific community has made some dramatic advances in the ability to chemically synthesize genome-length strands of DNA.¹ These advances have coincided with a growing understanding of the functions of individual genes and gene networks.² 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.³ The J. Craig Venter Institute took the first steps toward this goal by creating a synthetic organism controlled entirely by a chemically synthesized genome.⁴ This advance provided:

a proof of principle for producing cells based on computer-designed genome sequences. DNA sequencing of a cellular genome allows storage of the genetic instructions for life as a digital file [T]he approach [] developed [by the J. Craig Venter Institute] should be applicable to the synthesis and transplantation of more novel genomes as genome design processes.⁵

Although this ultimate goal of designing novel synthetic organisms using synthetic biology sounds like pure science fiction, it is entirely possible and would have an enormous impact on

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

² Matthias Heinemann & Sven Panke, *Synthetic Biology—Putting Engineering Into Biology*, 22 BIOINFORMATICS 2790, 2790 (2006).

³ See Gibson et al., *supra* note 1, at 55.

⁴ *Id.*

⁵ *Id.* at 52.

biotechnology and medicine. In the near future, 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.⁶ 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. From this older technology, however, the technology of synthetic biology has begun to emerge. 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 potentially stifling effects of DNA patents by establishing an open-source movement.⁷ The hope is that an open-source synthetic biology commons would encourage innovation in ways similar to the wildly successful open-source software movement.⁸ Towards that end, a similar open-source approach to synthetic biology might be useful.⁹ The world of synthetic biology, however, poses unique problems to the establishment of an open-source community. These problems include incentivizing entities to participate, maintaining openness once it is established, and creating useable biomedical products.¹⁰

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. Part IV describes the past strategies used to establish and maintain other analogous open-source biotechnology movements. Within Part IV, 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. Next, Part VI 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

⁶ See generally, Heinemann & Panke, *supra* note 2.

⁷ *About the BioBricks Foundation*, BIOBRICKS, <http://biobricks.org/about-foundation/> (last visited Feb. 11, 2012).

⁸ *Id.*

⁹ *Id.*

¹⁰ See, Andrew W. Torrance, *Synthesizing Law For Synthetic Biology*, 11 MINN. J.L. SCI. & TECH. 629, 650–51 (2010).

organization. Part VII will conclude that a standard setting organization for synthetic biology may help to overcome problems that cannot be addressed under the three previously described strategies.

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 that encodes the instructions for life.¹¹ The DNA language uses four nucleotides—adenine, thymine, cytosine, and guanine—organized in specific sequences to compose the genes responsible for heritable traits.¹² The DNA sequence of an organism gets copied with an extremely high fidelity, averaging only one nucleotide error for every billion nucleotides copied.¹³ This DNA sequence is passed on to offspring, transmitting genetic information from generation to generation.¹⁴

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.¹⁵ 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.¹⁶ 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.¹⁷ The advent of the above methods, however, has made DNA one of the easiest molecules to manipulate.¹⁸

Presently, DNA manipulation techniques have 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.¹⁹ Scientists have used this recombinant DNA technology (“rDNA technology”) in

¹¹ BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 193 (4th ed. 2002).

¹² *Id.* at 194.

¹³ *Id.* at 236.

¹⁴ *Id.* at 195.

¹⁵ *Id.* at 492.

¹⁶ *Id.*

¹⁷ ALBERTS ET AL., *supra* note 11, at 491.

¹⁸ *Id.*

¹⁹ *Id.* at 493.

numerous applications, impacting various fields including medicine, research, and agriculture.²⁰ Despite these advances, however, rDNA technology has limited scientists in some ways.²¹ Generally, rDNA techniques involve manipulating a small number of genes with each modification involving a time consuming procedure.²² Most scientific advances using rDNA technology involves the engineering of a single gene because of the time constraints and scientists' superficial understanding of how genes work alongside one another.²³ For example, recombinant human insulin, which has almost entirely replaced insulin derived from animal sources,²⁴ is synthesized by expressing a single human insulin gene in the bacteria *E. Coli*.²⁵ 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.²⁶ 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.²⁷

²⁰ ALBERTS ET AL., *supra* note 11, at 491 (rDNA technology has been used in the classification of genes/proteins and studying regulatory networks of genes); M.J. The, *Human Insulin: DNA Technology's First Drug*, 46 AM. J. OF HOSP. PHARMACY 11 (Nov. 1989) (mass production of human insulin as a replacement for insulin derived from animal sources); *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).

²¹ See, e.g., Suzanne Cheng, Carita Fockler, Wayne M. Barnes & Russel Higuchi, *Effective Amplification of Long Targets From Cloned Inserts and Human Genomic DNA*, 91 PROCEEDINGS OF THE NAT'L ACAD. OF SCIENCES 5695 (1994). It is possible to PCR amplify sequences of DNA up to approximately forty-thousand bases. *Id.* at 5698. For comparison, the human genome is billions of bases long.

²² 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) (explaining that even the simplest cloning procedure involves many steps and will take several days to complete).

²³ Subin Mary Zachariah & Leena K. Pappachen, *A Study of Genetic Engineering Techniques In Biotechnology Based Pharmaceuticals*, 3 INTERNET J. 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>.

²⁴ The, *supra* note 20.

²⁵ *Id.*; INSULIN RECOMBINANT, DRUGBANK.CA, <http://www.drugbank.ca/drugs/DB00030> (last visited Nov. 5, 2011).

²⁶ The, *supra* note 20.

²⁷ See generally, Heinemann & Panke, *supra* note 2.

B. Defining the New Technology of Synthetic Biology

There is no bright line that distinguishes the older rDNA technology from the new synthetic biology.²⁸ Scientists began using the latter term 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. Drew Endy, one of the pioneers of synthetic biology, stated that for the biologist, the term means “the ability to design and construct synthetic biological systems [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 refers to as “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 machine. This Comment adopts this definition because the technological capability of designing standardized biological parts is necessary for the establishment of open-source synthetic biology.³⁴

²⁸ See Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449, 449 (2005).

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

³⁰ Endy, *supra* note 28, at 449.

³¹ *Id.*

³² *Id.* (internal citation omitted).

³³ *Id.*

³⁴ See David W. Opderbeck, *The Penguin’s Genome, or Coase and Open Source Biotechnology*, 18 HARV. J.L. & TECH. 167, 168 (2004). Professor Opderbeck reviews

The definition is largely drawn from 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.³⁷ Unfortunately, current rDNA techniques largely lack any kind of standardization, which severely reduces the pace of technological innovation.³⁸ Building a car from scratch is analogous. An experienced 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. In other words, the parts of a car are known to be interoperable because there have been "standards" adopted by the community of engineers that build them.³⁹ Now, imagine the challenge of building a car from

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

³⁵ See *id.* Professor Opderbeck points out that rDNA technology poses some technical problems with respect to component "layers" in the context of open source biotechnology. *Id.* at 181–82. 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 Opderbeck also notes that to establish open source biotechnology, there must exist social-psychological rewards and a community of contributors with authoritative voices. *Id.* at 186–97. While these two factors are outside the scope of this Comment, the BioBricks 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 J. BIOLOGICAL ENGINEERING 1, 1 (2008), available at <http://www.jbioleng.org/content/2/1/5>.

³⁷ See Endy, *supra* note 28.

³⁸ See Endy, *supra* note 28, at 450.

³⁹ See Smita B. Brunnermeier & Sheila A. Martin, *Interoperability Cost Analysis of the U.S. Automotive Supply Chain*, RESEARCH TRIANGLE INSTITUTE (Mar. 1999), available

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, resulting in a significantly longer completion time. This problem is compounded when working with 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.⁴⁰ Presently, all engineering of novel gene networks requires a significant amount of trial and error during development.⁴¹ For this reason, without standardized biological parts, the pace of innovation would be extremely slow.

To make this point, Endy uses the example of creating a biological oscillator.⁴² An electrical engineer could create several working ring oscillators in under an hour.⁴³ In the biological context, however, it took two of the world's best biophysicists a year to make an analogous biological oscillator.⁴⁴ The main difference between the two is that electrical engineers have standard parts available to them that work predictably and reliably, while molecular biologists do not.⁴⁵ 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 field that would benefit from an increase in the pace of progress is medicine. Recently, scientists have taken a synthetic biology approach to engineer biological systems as novel therapies in a pre-clinical setting.⁴⁶ For example, scientists engineered a bacteriophage (a virus that infects bacterium) that can destroy bacterial biofilms resistant to antibiotics.⁴⁷ Another example is bacteria engineered to invade cancer cells in a solid tumor.⁴⁸ A synthetic organism is even being developed to modify the “human microbiome,” the endogenous ecosystem of bacteria found in all

at http://www.rti.org/pubs/US_Automotive.pdf.

⁴⁰ See generally Wendell A. Lim, Connie M. Lee, & Chao Tang, *Design Principles of Regulatory Networks: Searching for the Molecular Algorithms of the Cell*, 49 *MOLECULAR CELL* 202 (2013).

⁴¹ See generally Endy, *supra* note 28.

⁴² Endy, *supra* note 28 at 449; see generally Warren C. Ruder, Ting Lu, & James J. Collins, *Synthetic Biology Moving into the Clinic*, 333 *SCIENCE* 1248, 1249 (2011).

⁴³ Endy, *supra* note 28, at 449.

⁴⁴ *Id.*

⁴⁵ See *id.*, at 450.

⁴⁶ See Ruder, Lu & Collins, *supra* note 42, at 1251.

⁴⁷ *Id.*

⁴⁸ *Id.*

healthy people, which is required for normal physiology.⁴⁹ Scientists are engineering the microbiome bacterium to live in the human gut with the ability to prevent the secretion of toxins from cholera.⁵⁰ Scientists have engineered other bacteria to secrete various factors to treat diabetes or HIV.⁵¹ 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.⁵²

All of these advances were the result of manipulating genomes by removing and/or adding various parts to alter biological pathways.⁵³ 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.⁵⁴ But in order to be possible in human beings, “it will be necessary to identify entirely new modules and components from endogenous networks as well as to synthesize and characterize diverse component libraries.”⁵⁵ In order to support human application, scientists will require a substantial increase in the degree of control over the behavior of synthetic organisms.⁵⁶ The scientific community has 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 scientists make advances, the sooner they can develop novel therapies to treat human disease.

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.⁵⁷ Tens of thousands of human genes are patented by various companies who solely own the patent rights to

⁴⁹ *Id.* at 1250.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² Ruder, Lu, & Collins, *supra* note 42, at 1294.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.* at 1251.

⁵⁶ *See id.*

⁵⁷ *See* Sam Kean, *The Human Genome (Patent) Project*, 331 *SCIENCE* 530, 530 (2011).

use them.⁵⁸ Many commentators have posited that these patent rights slow the pace of progress in biomedical sciences dramatically.⁵⁹ Emerging technologies are, by their very nature, especially vulnerable to broad patents that suppress innovation.⁶⁰ 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.⁶¹ This is because the technology that a foundational patent covers is necessarily incorporated into any downstream research or resulting product.⁶²

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.⁶³ Once foundational biological parts are made publicly available in such a commons, individual entities would not have the right to patent them.⁶⁴ Furthermore, some commentators have argued that this strategy has the added benefit of encouraging innovation.⁶⁵ This “open-source” approach to synthetic biology is analogous to the open-source software movement which was wildly successful as it resulted in the creation of countless computer applications including the Linux operating system.⁶⁶

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 to

⁵⁸ *Id.* at 531.

⁵⁹ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–99 (1998) (arguing that patents over various biomedical technologies may result in an “anticommons” where intellectual property rights result in underutilization of technology that hinders advancement).

⁶⁰ *Id.* at 698.

⁶¹ See *id.*; Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745, 1757 (2007).

⁶² See Heller & Eisenberg, *supra* note 59, at 698.

⁶³ 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>.

⁶⁴ See 35 U.S.C. § 102(a) (2006).

⁶⁵ See Torrance, *supra* note 10, at 650–51.

⁶⁶ *Id.* at 654.

launch an open-source community.⁶⁷ Subsection III.A will describe both what it means to be “open-source” and the terms used to maintain openness in the context of computer software. Subsection III.B will discuss the open-source strategy of the BioBricks Foundation. Subsection 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.⁶⁸ 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.⁶⁹ The OSI uses ten different terms of distribution, all of which are written with software development in mind.⁷⁰ But each term can be applied to other technologies where non-rivalrous information⁷¹ is being freely distributed, including the technology of synthetic biology. The most important OSI requirements to ensure openness are: allowing free redistribution, allowing derived works, and allowing a distribution of licenses.⁷² 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.”⁷³ The derived-works term states that “[t]he 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.”⁷⁴ Lastly, the distribution of license term states that “[t]he rights attached to the program must apply to all to whom the program is redistributed

⁶⁷ *About the BioBricks Foundation*, *supra* note 7.

⁶⁸ *Open Source Definition*, OPENSOURCE, <http://www.opensource.org/osd.html> (last visited Feb. 11, 2012).

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ 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.”).

⁷² *Open Source Definition*, *supra* note 68.

⁷³ *Id.*

⁷⁴ *Id.*

without the need for execution of an additional license by those parties.”⁷⁵ 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.⁷⁶ 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.⁷⁷

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 ethical, open innovation.”⁷⁸ Toward that end, the BioBricks Foundation has established a synthetic biology commons where various DNA “parts” are made freely available for public use, applying open-source software principles.⁷⁹

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.⁸⁰ 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.⁸¹ The main goal of this open strategy is to “make biology easier to engineer so as to benefit all people and the planet. Today, it is difficult to share and reuse genetically encoded functions due to high transaction costs associated with patent-based licensing (i.e., time and money).”⁸² The contracts contain some terms that are analogous to OSI terms of distribution.⁸³ The BioBricks Public Agreement is described as “a

⁷⁵ *Id.*

⁷⁶ 17 U.S.C. § 101 (2006) (Literary works include words, numbers, or other indicia, regardless of the nature of its embodiment).

⁷⁷ See BIOBRICKS, <http://biobricks.org> (last visited Apr. 2, 2013) (“We believe fundamental scientific knowledge belongs to all of us and must be freely available for ethical, open innovation.”).

⁷⁸ *Id.*

⁷⁹ *About the BioBricks Foundation*, *supra* note 7.

⁸⁰ *The BioBrick Public Agreement*, BIOBRICKS, <https://biobricks.org/bpa/> (last visited Apr. 2, 2013).

⁸¹ *Id.*

⁸² *Frequently Asked Questions*, BIOBRICKS, <https://biobricks.org/bpa/faq/> (last visited, Apr. 2, 2013).

⁸³ *Compare The BioBrick Contributor Agreement*, BIOBRICKS,

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.”⁸⁴ There are two distinct types of contract—one for the “Contributor” and one for the “User.”⁸⁵ The Contributor is the person making the biological part available, while the User is the person utilizing the part that the contributor provided.⁸⁶ The Contributor contract states that a BioBricks Contributor makes “an irrevocable promise not to assert any existing or future intellectual property rights over the something against the other party to the contract.”⁸⁷ 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.⁸⁸ 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.”⁸⁹

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.⁹⁰ Rather, the terms of the BioBricks Public Agreement are “an initial effort to draft a legal constitution to guide the beneficial development of the field of synthetic biology.”⁹¹

C. Challenges Maintaining the BioBricks Commons

There are several significant challenges to the openness of the BioBricks commons. Importantly, the BioBricks Public Agreement does not include some provisions included in the OSI terms of distribution.⁹² Three of these challenges will be discussed specifically in this section. The first challenge is *derivation*: getting contributors to donate derived work back to the BioBricks Foundation and not

<http://biobricks.org/wp-content/themes/bbf/bpa-sample.php> (last visited Feb. 12, 2012), with *Open Source Definition*, *supra* note 68.

⁸⁴ *Frequently Asked Questions*, *supra* note 82.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *The BioBricks Contributor Agreement*, *supra* note 83 (section 4, Intellectual Property Rights).

⁸⁹ *Frequently Asked Questions*, *supra* note 82; see *The BioBricks User Agreement*, BIOBRICKS, <http://biobricks.org/bpa/users/agreement/> (last visited Feb. 12, 2012).

⁹⁰ Torrance, *supra* note 10, at 663.

⁹¹ *Id.*

⁹² See *Frequently Asked Questions*, *supra* note 82.

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assert any intellectual property rights.⁹³ 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.⁹⁴ 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.⁹⁵ The first two challenges stem from the terms of the BioBricks Public Agreement, while the third challenge is inherent in biomedically relevant research.⁹⁶ Each challenge will be considered in turn.

1. Derivation

One of BioBricks Foundation's open-source community goals is to foster the creation of novel biological parts by derivation from the parts currently found in the registry.⁹⁷ Despite this goal, 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 a User is the inventor of the biological part, she is barred from asserting any intellectual property rights over any individual biological part once contributed to the BioBricks Foundation.⁹⁸ But there is nothing stopping a user from asserting intellectual property rights over a different biological part that is *derived from BioBricks parts*.⁹⁹ In other words, if a person has signed the BioBricks User Agreement and, in using the BioBricks parts, creates a new part with a novel function, there is 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.¹⁰⁰ The BioBricks Foundation makes perfectly clear that "[n]ovel materials and applications produced using [contributed] parts may be considered for protection via conventional property rights."¹⁰¹ As a result, the BioBricks User

⁹³ See generally Torrance, *supra* note 10.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ See *About the BioBricks Foundation*, *supra* note 7.

⁹⁸ See 35 U.S.C. § 102 (2006).

⁹⁹ This statement assumes that the derived work is both novel and non-obvious. See generally 35 U.S.C. §§ 102, 103 (2006).

¹⁰⁰ *Frequently Asked Questions*, *supra* note 82.

¹⁰¹ *Id.*

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.¹⁰² Without a reciprocal licensing mechanism in place to ensure that novel biological parts will continue to be derived from the past work of users, maintaining a cycle of innovation by participants in the synthetic biology commons may be challenging.

2. Motivation

A second important problem 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 to forego one's intellectual property rights is to make a philanthropic gesture.¹⁰³ 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."¹⁰⁴

3. End Product

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.¹⁰⁵ Other open-source movements, such as the open-source software movement, were wildly successful in part due to the fact that a working product resulted from the aggregate work of many individuals.¹⁰⁶ The quintessential example of open-source success is the Linux operating system.¹⁰⁷ It can be downloaded and used by anyone in the world after thousands of individuals put forth effort over many years to make it.¹⁰⁸ That is not always the case with

¹⁰² Compare *The BioBricks Contributor Agreement*, *supra* note 83, with *Open Source Definition*, *supra* note 68.

¹⁰³ Torrance, *supra* note 10, at 660.

¹⁰⁴ *Id.*

¹⁰⁵ 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.").

¹⁰⁶ See, e.g., LINUX, <https://www.linux.com/learn/new-user-guides/376-linux-is-everywhere-an-overview-of-the-linux-operating-system> (last visited Sept. 7, 2013).

¹⁰⁷ See DOWNLOAD LINUX FREE, <http://downloadlinuxfree.com/> (last visited Apr. 6, 2012).

¹⁰⁸ *Id.*

biotechnology.¹⁰⁹ If members of the BioBricks Foundation were to engineer a microbe to be a medical therapy, the end product could not be immediately used.¹¹⁰ Instead, introduction of the product would require lengthy and extremely costly clinical trials as a drug, biologic, or medical device.¹¹¹ It is likely that an entire community of BioBricks members would not have the knowledge or resources available to undertake this task.

Thus, there are several problems to overcome in establishing a viable open-source synthetic biology movement. The first is getting people and corporations to make their derived works, which may be very valuable, available for further public use free of charge.¹¹² The second issue is getting people and corporations with intellectual property rights to contribute parts.¹¹³ The third, in the context of designing a medical therapy, is getting a synthetic biology product through clinical trials so that it will actually be beneficial.¹¹⁴

The first two problems have been previously addressed by other open-source movements, such as software development and human gene haplotype sequencing, which also had to deal with the threat of patents stifling progress.¹¹⁵ In the context of those specific technologies, several different strategies were devised to maintain openness. Parts IV and V will address three strategies that have been applied to other technologies that potentially can be applied to maintaining open-source synthetic biology.¹¹⁶ Each of the following strategies previously has been evaluated in the context of a specific technology and each has been successful in maintaining some degree of openness.¹¹⁷ Part IV will introduce these previously proposed strategies. Part V will answer the question of whether any of the proposed strategies are applicable to a synthetic biology commons, and if so, whether any would be successful. This Comment will evaluate three strategies: Copyright Open-Source approach, the HapMap License approach, and the BiOS patent approach.

¹⁰⁹ See Munos, *supra* note 105.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² See generally, Torrance, *supra* note 10.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ See *infra* Part IV.

¹¹⁶ See *infra* Part IV & V.

¹¹⁷ See *infra* Part IV.

IV. PREVIOUSLY PROPOSED OPEN-SOURCE STRATEGIES

A. *Copyright Open-Source Approach*

Currently, copyright protection for sequences of DNA is not available.¹¹⁸ If sequences of DNA *could* be protected under Copyright Law, however, then it would be relatively straightforward to implement open-source synthetic biology in an analogous fashion to open-source software.¹¹⁹ A license to use the DNA “work” would include provisions that require the user to give back to the commons any derivative works.¹²⁰ The General Public License (GPL)¹²¹ that has been commonly used in open-source software could be easily adapted to cover DNA¹²² 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.¹²³ Some observers even suggested that this approach could be used to establish open-source synthetic biology.¹²⁴ These scholars reasoned that DNA sequences are very similar to computer software code because both involve a set of software instructions that are first read and then executed by hardware.¹²⁵ Additionally, any unique issues that might arise in the context of synthetic biology could be absorbed with a relatively small incremental change to copyright law.¹²⁶

For example, Dr. Christopher Holman makes the case that

¹¹⁸ See MICHAEL 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).

¹¹⁹ See Torrance, *supra* note 10; Christopher M. Holman, *Copyright For Engineered DNA: An Idea Whose Time Has Come?*, 113 W. VA. L. REV. 699 (2011).

¹²⁰ *GNU General Public License, Version 3*, OPENSOURCE, <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.”).

¹²¹ *Id.*

¹²² Holman, *supra* note 119 (arguing that 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).

¹²³ See *id.*; Torrance, *supra* note 10.

¹²⁴ Holman, *supra* note 119; Torrance, *supra* note 10.

¹²⁵ Holman, *supra* note 119, at 712.

¹²⁶ Holman, *supra* note 119; Torrance, *supra* note 10.

engineered DNA should be protected by copyright law.¹²⁷ He argues that “[t]he 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.”¹²⁸ Dr. Holman argues that engineered sequences of DNA and computer code both are essentially sets of instructions that are read and executed by hardware.¹²⁹ For computer code, the hardware is the group of computer components itself; for DNA sequences, the hardware is the group of proteins, carbohydrates, and fatty acids that make up a living cell.¹³⁰ Furthermore, advances in biotechnology have allowed a high level of creativity in generating DNA sequences.¹³¹ This is important because the Supreme Court, in *Feist Publications, Inc. v. Rural Telephone Service Co. Inc.*,¹³² established a minimum threshold for a work to be covered by copyright law—the work must contain “a modicum of creativity.”¹³³ This is a relatively low threshold that could be easily met even with the current state of synthetic biology because the technology currently allows for the creation of DNA sequences that are different—at least modestly—from what exists in nature.¹³⁴

Moreover, in recent years the Supreme Court has consistently interpreted the Copyright Clause of the constitution broadly.¹³⁵ For example, in the context of the Copyright Clause, the Supreme Court does not interpret the term “writing” literally—photographs, art, motion pictures, and sounds have all been considered “writings.”¹³⁶ And Congress and the Courts have expanded what constitutes a “writing” for the purposes of the Copyright Clause to adapt to evolving technology.¹³⁷ At one point in time, the only expressions deemed protectable were those which a human could directly

¹²⁷ See Holman, *supra* note 119.

¹²⁸ *Id.* at 703.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Feist Publ’n, Inc. v. Rural Tel. Serv. Co., Inc.*, 499 U.S. 340 (1991).

¹³³ *Id.* at 346.

¹³⁴ See generally Ruder, Lu & Collins, *supra* note 42.

¹³⁵ See Holman, *supra* note 119.

¹³⁶ See *Goldstein v. California*, 412 U.S. 546 (1973); *Kalem Co. v. Harper Bros.*, 222 U.S. 55 (1911); *Bleistein v. Donaldson Lithographing Co.*, 188 U.S. 239 (1903); *Burrow-Giles Lithographic Co. v. Sarony*, 111 U.S. 53 (1884).

¹³⁷ Holman, *supra* note 119, at 710.

perceive, such as written words.¹³⁸ But in 1976 Congress explicitly expanded the scope of copyright protection to include expressions that could only be read by a machine.¹³⁹ Through the 1980's, computer software was generally accepted as a type of expression that could be protected by copyright, but there was some uncertainty over the scope of protection.¹⁴⁰ Dr. Holman sums up the uncertainty:

[D]id copyright protection extend to object code, which could only be read by a computer, or was it limited to human readable source code? What about operating system software, whose only intended audience is a machine? Or a computer program embodied in computer readable media, such as a CD-ROM? Ultimately, all these questions are answered in the affirmative.¹⁴¹

Presently, there is a general consensus in the Courts that copyright protection is available for *any* type of software, regardless of its form or the medium in which it is stored.¹⁴² And considering the expansion of copyright protection in response to changing technology, there is good reason to believe that a molecule of DNA could be considered merely another type of code analogous to computer software 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.¹⁴³ 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.¹⁴⁴ This is seemingly equivalent to the freedom of a computer programmer to create any form of program, constrained only by the computer language and hardware itself. Indeed, Torrance even notes that “one of the primary goals of synthetic biology is to engineer cells and genes to become ever more like computers and computer software.”¹⁴⁵ If this approach is adopted, then DNA is already

¹³⁸ See *White-Smith Music Publ'g Co. v. Apollo Co.*, 209 U.S. 1 (1908).

¹³⁹ See 17 U.S.C. § 102 (a) (2006).

¹⁴⁰ Holman, *supra* note 119, at 710–11.

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ Torrance, *supra* note 10, 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.”).

¹⁴⁴ See Endy, *supra* note 28.

¹⁴⁵ Torrance, *supra* note 10, at 647.

protected by the Copyright Act and no adaptation of law is needed in order to protect sequences of DNA.

B. HapMap Licensing Approach

Some open-source movements have been relatively successful in using a contract-based license to create an information commons in the realm of biotechnology.¹⁴⁶ One in particular, the International HapMap Project, was a joint public-private venture between several universities and government agencies from around the world to map genetic variation among the world's human population.¹⁴⁷ The stated goal of the HapMap Project was to “help researchers find genes associated with human disease and response to pharmaceuticals.”¹⁴⁸ 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.”¹⁴⁹ 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.¹⁵⁰ The HapMap Consortium reasoned that enough data on human genetic variation was published such that any patent applications derived from HapMap data would be considered obvious and therefore not patentable.¹⁵¹ Since then, all access to HapMap haplotype data is freely accessible to anyone without having to sign a license agreement.¹⁵²

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.¹⁵³ This mandatory licensing agreement stated that “you will have to agree to a single condition—

¹⁴⁶ See *About the International HapMap Project*, INT'L HAPMAP PROJECT, <http://hapmap.ncbi.nlm.nih.gov/abouthapmap.html> (last visited Apr. 6, 2012).

¹⁴⁷ *Id.*

¹⁴⁸ THE INTERNATIONAL HAPMAP PROJECT, <http://hapmap.ncbi.nlm.nih.gov> (last visited Feb. 11, 2012).

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, 1483 (2007).

¹⁵⁰ *Id.*

¹⁵¹ See 35 U.S.C. § 103 (2012); Gitter, *supra* note 149, at 1485; *NIH News Release*, GENOME.GOV, <http://www.genome.gov/12514423> (last visited Feb. 12, 2012).

¹⁵² *Data Access Policy for the International HapMap Project*, THE INTERNATIONAL HAPMAP PROJECT, <http://hapmap.ncbi.nlm.nih.gov/cgi-perl/registration> (last visited Feb. 11, 2012).

¹⁵³ *Id.*

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.”¹⁵⁴ The licensing agreement also prohibited distribution of data from the HapMap project to parties that had not accepted the terms of the license.¹⁵⁵ 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.¹⁵⁶ The Center for the Application of Molecular Biology to International Agriculture created the BiOS initiative in “response to inequities in food security, nutrition, health, natural resource management and energy.”¹⁵⁷ BiOS currently holds the intellectual property rights to several technologies relevant to food production.¹⁵⁸ For example, BiOS holds patents on several plant technologies, including the plant-gene transfer methods, generation of plant-gene fusions, and methods for genotyping genetically engineered plants.¹⁵⁹ 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.¹⁶⁰ 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 [sic] provided for the original core technology.”¹⁶¹

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ BiOS is an initiative of the Center for the Application of Molecular Biology to International Agriculture (CAMBIA). See CAMBIA, <http://www.cambia.org/daisy/cambia/home.html> (last visited, Feb. 12, 2012).

¹⁵⁷ BiOS, <http://www.bios.net/daisy/bios/home.html> (last visited Feb. 11, 2012).

¹⁵⁸ *IP Portfolio Licensable from Cambia*, CAMBIA, http://www.cambia.org/daisy/cambialabs/ip_portfolio.html (last visited Feb. 11, 2012).

¹⁵⁹ *Id.*

¹⁶⁰ 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 *id.*

¹⁶¹ Robin Feldman, *The Open Source Biotechnology Movement: Is it Patent Misuse?*, 6 MINN. J.L. SCI. & TECH. 117, 128 (2004).

Some academics, such as Professor Robin Feldman, suggest that this grant-back requirement may implicate patent misuse.¹⁶² 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.¹⁶³ “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.”¹⁶⁴ While nothing necessarily precludes someone from bringing a claim against BiOS, 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 grant-back requirement is not inconsistent with patent policy and any anti-competitive effects are outweighed by the pro-competitive benefits.¹⁶⁵ Professor Feldman comes to this conclusion by applying a two-part test to the open-source grant-back requirement.¹⁶⁶ The first part asks whether the grant-back requirements of the patent holder are inconsistent with patent policy.¹⁶⁷ The second part asks whether the grant-back requirement fails the antitrust rule of reason.¹⁶⁸ In the case of the BiOS initiative, the grant-back requirement is compatible with patent policy because it is not intended to create exclusive use of any technology; rather, it is intended to promote widespread use and foster innovation.¹⁶⁹ And the grant-back requirement would not violate anti-trust principles because it has the effect of maximizing the amount of improved technology that is openly available, rather than reduce competition in a technology market.¹⁷⁰ Thus, Professor Feldman argues that open source biotechnology movements should not be considered patent misuse because the grant-back requirement does not fail either test.

V. APPLICATION OF PAST STRATEGIES TO SYNTHETIC BIOLOGY

The previous open-source strategies described in Part IV lead to the question of whether any of the copyright, license, or patent-based

¹⁶² *Id.* at 142.

¹⁶³ *Id.* at 118–19.

¹⁶⁴ *Id.* at 141–42.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ Feldman, *supra* note 161, at 141–42.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

approaches to maintaining openness would work in the context of synthetic biology. This section applies these 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 these strategies 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,¹⁷¹ there is currently no indication that the U.S. Copyright Office or Congress would approve the use of Copyright Law to protect DNA sequences.¹⁷² Also, scholars such as Andrew Torrance, Sapna Kumar and Arti Rai have all pointed out that the Copyright approach may not work for DNA sequences that already exist in nature.¹⁷³ Indeed, copyright law is intended to prevent verbatim copying of a writing, regardless of whether the writing is in the form of computer software or DNA sequence.¹⁷⁴ And copyright law does not extend to “discoveries” and thus, no naturally occurring sequences of DNA could be protected under a Copyright.¹⁷⁵ While designing novel DNA sequences that do not exist in nature may become commonplace in the future through synthetic biology, the current state of the technology largely involves previously existing

¹⁷¹ See Holman, *supra* note 119, at 703; Torrance, *supra* note 10, at 647.

¹⁷² See Holman, *supra* note 119, at 702.

¹⁷³ See generally Torrance, *supra* note 10; Kumar & Rai, *supra* note 61 (stating that the copyright clause of the constitution was intended to protect the creative works of authors, it would not apply to naturally occurring sequences of DNA because those sequences would not be creative works having an author).

¹⁷⁴ 17 U.S.C. § 101 (2012) (“Copies are material objects . . . in which a work is fixed by any method now known or later developed.”).

¹⁷⁵ 17 U.S.C. § 102 (b) (2012) (“In no case does copyright . . . extend to any . . . *discovery*, regardless of the form in which it is described, explained, illustrated, or embodied.”) (emphasis added).

genetic code.¹⁷⁶ For example, the vast majority of BioBricks parts made available in the registry are sequences of DNA taken directly from naturally occurring organisms.¹⁷⁷

While the applicability of copyright law to sequences of DNA is untested,¹⁷⁸ the Supreme Court's recent views on intellectual property rights of DNA suggest copyright protection may, in theory, be possible.¹⁷⁹ While no court has *directly* indicated that it would approve or disapprove the use of Copyright to protect sequences of DNA, there is some *indirect* indication that it might be receptive to copyright protection for novel sequences of DNA.¹⁸⁰ *The Association for Molecular Pathology v. United States Patent and Trademark Office* (Myriad gene patent case)¹⁸¹ offers some insight into how the U.S. courts view intellectual property rights surrounding sequences of DNA. While patents and copyrights are distinct bodies of intellectual property law, the Supreme Court's reasoning in the gene patent cases may be an indication of future willingness to allow copyright protection for DNA.¹⁸²

In July of 2011, the original Myriad gene patent decision, authored by Judge Sweet in the Southern District of New York, held that a composition of isolated genomic DNA was not patentable

¹⁷⁶ See, e.g., *Promoters/Catalog/Constitutive*, PARTSREGISTRY, <http://partsregistry.org/Promoters/Catalog/Constitutive> (last visited Feb. 12, 2012) (In this example category, all of the BioBricks's constitutively active promoter sequences have been cloned from a naturally occurring organism; each sequence has a prokaryotic, eukaryotic, or phage origin.).

¹⁷⁷ *Id.*

¹⁷⁸ See MICHAEL 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).

¹⁷⁹ See *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff'd in part & rev'd in part*, 689 F.3d 1303 (Fed. Cir. 2012), *aff'd in part & rev'd in part*, 133 S. Ct. 2107 (2013).

¹⁸⁰ *See id.*

¹⁸¹ *Id.*

¹⁸² See *Ass'n for Molecular Pathology*, 689 F.3d 1303 (Fed. Cir. 2012), *aff'd in part & rev'd in part*, 133 S. Ct. 2107 (2013). 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; in the context of a whole chromosome. The patentability of isolated *genomic* DNA was the subject of dispute among the three-judge panel in the Federal circuit and was ruled patent ineligible by the Supreme Court. See *Ass'n of Molecular Pathology*, 689 F.3d 1303, *aff'd in part & rev'd in part*, 133 S. Ct. 2107 (2013).

subject matter.¹⁸³ Judge Sweet seized on the idea that DNA is a carrier of *information* and that this property gives it utility.¹⁸⁴ Any isolated DNA containing the same sequence information of native DNA is therefore a product of nature and unpatentable.¹⁸⁵

On August 16, 2012, a three-Judge panel in the Federal Circuit handed down three separate opinions, resulting in a reversal of Judge Sweet's decision.¹⁸⁶ Two out of the three judges on the Federal Circuit panel completely rejected Judge Sweet's reasoning, and concluded that isolated genomic DNA was patent eligible.¹⁸⁷ Judge Lourie held that "it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility" rather than the utility of informational content.¹⁸⁸ Furthermore, Judge Lourie stated that when determining patent eligibility of DNA, the "informational content is irrelevant."¹⁸⁹ Judge Moore concurred with Judge Lourie on the issue of patent eligibility of isolated genomic DNA sequences, but wrote separately to emphasize the utility of small isolated fragments of DNA and the tacit approval by the United States Patent and Trademark Office and congress.¹⁹⁰ Judge Bryson's opinion, however, followed Judge Sweet's original reasoning, concluding that "[t]he nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes."¹⁹¹ Thus, Judge Bryson emphasized the information carrying property of DNA rather than its physical structure.¹⁹²

Most recently, on June 13, 2013, the Supreme Court unanimously held that isolated sequences of genomic DNA are not patent eligible subject matter.¹⁹³ Justice Thomas, writing for the majority, stated that the patent claims at issue "focus on the genetic information encoded in the [DNA]."¹⁹⁴ Justice Thomas pointed out

¹⁸³ *Ass'n for Molecular Pathology*, 702 F. Supp. at 227–28.

¹⁸⁴ *Id.* at 228–29.

¹⁸⁵ *Id.* at 227–29.

¹⁸⁶ *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (2012).

¹⁸⁷ *See id.* at 1303 (2012).

¹⁸⁸ *Id.* at 1330.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 1341–46.

¹⁹¹ *Id.* at 1355.

¹⁹² *Id.*

¹⁹³ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

¹⁹⁴ *Id.* at 2118.

that this emphasis on information is necessary for patent protection because otherwise, a would-be infringer could avoid offending any patent claims by merely adding a single nucleotide base pair to the patented gene, thereby creating a distinctive molecule.¹⁹⁵ Thus, in order for a patent claim to offer any real protection from infringement, the patent claim must be “concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.”¹⁹⁶ Importantly, the Supreme Court also affirmed the District Court’s and Federal Circuit’s holding that cDNA sequences, which do not exist in nature, are patent eligible.¹⁹⁷

Since the Supreme Court has agreed with Judge Sweet’s reasoning and emphasized the *information*-carrying qualities of DNA, a parallel argument could be made that copyright law should be able to protect novel DNA sequences. When the informational aspect of a molecule of DNA is emphasized, then one could reasonably argue that the genetic information is simply read and executed by other cellular machinery in a fashion analogous to a computer reading and executing software instructions.¹⁹⁸ Thus, if courts emphasize the informational aspect of DNA, then some judicial reasoning would exist in support of Holman’s and Torrance’s conclusion that copyright should be applicable to sequences of DNA much like copyright is applicable to computer software.¹⁹⁹

The Court’s willingness to apply copyright law to novel sequences of DNA is far from certain. With the Supreme Court’s decision in the Myriad gene patent case, patents are clearly available to protect novel sequences of DNA.²⁰⁰ As Kumar and Rai 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.”²⁰¹ Thus, despite the sound arguments for why DNA should be protected under copyright law, it is possible that the courts would be reticent to support its use in that context.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 2119.

¹⁹⁸ See Holman, *supra* note 119 at 712; Torrance, *supra* note 10 at 647.

¹⁹⁹ *Id.*

²⁰⁰ See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

²⁰¹ Kumar & Rai, *supra* note 61, at 1764.

B. Application of HapMap Strategy to the BioBricks Public Agreement

The application of a HapMap license approach to maintaining an open-source synthetic biology movement is possible, but it raises issues associated with privity and 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.²⁰² Both agreements contain terms that prohibit placing restrictions on the information, or part, that has been made available.²⁰³ Importantly, this strategy does not require any intellectual property right to bind the signing party to the terms of the license.²⁰⁴ Kumar and Rai note that “[t]his contractual alternative does not require an underlying property right. Instead, the contract simply imposes conditions as part of the price of access.”²⁰⁵ Furthermore, the online nature of a license-based strategy requires that the agreed upon web-based contract be enforceable.²⁰⁶ Professor Donna Gitter has noted that “courts generally enforce clickwrap agreements provided the licensee ‘receive[s] notice of the license terms before buying or using’ [the software] . . . [and] ‘has the ability to return [it] . . . if he does not agree with the terms’”²⁰⁷ Professor Gitter suggests that the HapMap user agreement fulfilled these threshold requirements for enforceability.²⁰⁸ The similar clickwrap nature of the BioBricks agreement suggests that it would likely fulfill these threshold requirements as well. There are, however, several issues that still must be overcome.

1. Third-Party Privity Problems

Third-parties not in privity of contract who gain access to BioBricks parts will create several problems that must be overcome. Privity of contract can be described as “that connection or relationship which exists between two or more contracting parties. It is essential to the maintenance of an action on any contract that there should subsist a privity between the plaintiff and defendant in respect of the matter sued on.”²⁰⁹ Professor Gitter has noted that a

²⁰² Compare *The BioBricks Contributor Agreement*, *supra* note 83, with *Data Access Policy for the International HapMap Project*, *supra* note 152.

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ Kumar & Rai, *supra* note 61, at 1765.

²⁰⁶ Gitter, *supra* note 149, at 1487.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *RML Corp. v. Lincoln Wood Prods., Inc.*, 67 Va. Cir. 545, 549 (2005), quoting

licensing agreement would not prevent third parties who have gained access without having signed the agreement from violating the agreement's terms.²¹⁰ 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 with the HapMap consortium."²¹¹ A similar problem exists in the BioBricks Public Agreement: any third party that obtains a BioBrick part without agreeing to the license would not be bound by its terms.²¹² The HapMap Consortium sought to overcome this problem by including terms in its licensing agreement that specifically prohibited dissemination of HapMap data to parties that have not signed an agreement.²¹³ 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."²¹⁴ A similar contradiction would exist in the context of the synthetic biology commons: the openness of the BioBricks parts could only be protected from third parties by severely restricting dissemination of the BioBricks parts.

The BioBricks Foundation has not, however, implemented this type of third-party restriction.²¹⁵ 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.²¹⁶ Due to the absence of dissemination restrictions, any third-party issues that existed at the outset of the HapMap project will likely be amplified greatly in the context of the BioBricks Foundation.

2. Enforcement Problems

In addition to the problems associated with third parties violating the terms of a license, there may also be enforcement problems with parties who have agreed to the license terms. For

the definition in Black's Law Dictionary (4th ed. 1976).

²¹⁰ Gitter, *supra* note 149, at 1487.

²¹¹ *Id.* at 1488–89.

²¹² *The BioBricks Contributor Agreement, supra* note 83, with *Data Access Policy for the International HapMap Project, supra* note 152.

²¹³ *Data Access Policy for the International HapMap Project, supra* note 152.

²¹⁴ Kumar & Rai, *supra* note 61, at 1764.

²¹⁵ *Frequently Asked Questions, supra* note 82.

²¹⁶ *Id.*

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.²¹⁷ There is no reason to believe that the patent would be void under this circumstance.²¹⁸ As Professor David Opderbeck 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.”²¹⁹ In terms of the BioBricks Public Agreement, although an individual could fail to disclose the existence of a pending patent on a biological part, the individual’s resulting patent would not thereby be invalidated due to this violation.²²⁰ Thus, users may disregard the terms of the BioBricks Public Agreement, which are meant to maintain openness, without any real recourse for the BioBricks Foundation.²²¹

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.”²²² This certainly applies to the BioBricks Foundation, which is also a non-profit organization and has limited financial resources.²²³ 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.²²⁴ 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.”²²⁵

²¹⁷ See Opderbeck, *supra* note 34, at 199.

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.*

²²² Gitter, *supra* note 149, at 1489.

²²³ *About the BioBricks Foundation*, *supra* note 7 (“The BioBricks Foundation (BBF) is a 501(c)(3) public-benefit organization founded in 2006.”).

²²⁴ See Gitter, *supra* note 149, at 1489.

²²⁵ *Id.* at 1491.

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.

Unlike the BiOS Initiative, the BioBricks Foundation does not currently hold the patent rights to any broad foundational patents.²²⁶ 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.”²²⁷ 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.²²⁸ 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.²²⁹ The BioBricks registry currently holds thousands of

²²⁶ Several members of the BioBricks Board of Directors hold patents as individuals, but there is no indication that the Foundation itself is assigned any patents. See, e.g., *Board of Directors*, BIOBRICKS, <http://biobricks.org/about-foundation/board-of-directors/> (Tom Knight, one of the founding members of BioBricks, holds over thirty patents).

²²⁷ Kumar & Rai, *supra* note 61, at 1765.

²²⁸ Other members of the BioBricks foundation could not claim to be the inventor of biological parts donated by individual contributors. See 35 U.S.C. § 102(f) (2006); see also Dennis Crouch, *With 102(f) Eliminated, Is Inventorship Now Codified in 35 U.S.C. 101? Maybe, but not Restrictions on Patenting Obvious Variants of Derived Information*, PATENTLYO (OCT. 04, 2012), <http://www.patentlyo.com/patent/2012/10/with-102f-eliminated-is-inventorship-now-codified-in-35-usc-101.html>.

²²⁹ *The Cost of Obtaining a Patent in the U.S.*, IPWATCHDOG, <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).

BioBricks parts.²³⁰ 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 feasible for the BioBricks Foundation.

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 past strategies that have been used for maintaining openness in different technological areas.²³¹ 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.²³² Each of the previous strategies discussed only address the problem of securing derived works of synthetic biology for use in the open-source community. The problems of motivating patent holders to donate biological parts in the first place and getting biomedical end products into the clinic are not addressed by the patent, copyright, or license approaches described in Parts IV and V. 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.”²³³ 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-

²³⁰ 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, http://partsregistry.org/Main_Page (last visited Apr. 6, 2012).

²³¹ See *supra* Part IV.

²³² See *supra* Part V.

²³³ Andrew Upgrove, *Forming a Successful Consortium*, THE ESSENTIAL GUIDE TO STANDARDS, <http://www.consortiuminfo.org/essentialguide/whatisansso.php> (last visited Feb. 12, 2012).

service or product.²³⁴ Standards are found everywhere in our daily life and their importance cannot be overstated. The classic example is an electrical plug and socket²³⁵—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 in the wall socket. Both the plug on the device and the electrical socket in the home are guaranteed to work together because the manufacturers of the product and the socket have adopted a standard. 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.”²³⁶ Thus, standards have the beneficial effects of promoting efficiency of innovation as well as competition in a marketplace.²³⁷

Standards can be broadly classified into three groups: de facto standards, private standards, and government standards.²³⁸ De facto standards arise naturally in a marketplace when users adopt a standard to the exclusion of any competition.²³⁹ 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 1990s.²⁴⁰ Finally, private standards are adopted voluntarily by members of an industry, usually after the formation of a private SSO.²⁴¹ With no requirement to join a private SSO, “some flourish, while others enjoy only middling success, and some fail to gain traction at all.”²⁴²

At the core of an SSO is the establishment of policies to deal with intellectual property rights, namely patents.²⁴³ To accomplish

²³⁴ *Id.*

²³⁵ *Multi-Standard Sockets*, THE DIGITAL MUSEUM OF PLUGS AND SOCKETS, <http://fam-oud.nl/~plugsocket/MultiSockets.html> (last visited Feb. 12, 2012).

²³⁶ Edith Ramirez, *The Federal Trade Commission Workshop on Intellectual Property Rights in Standard Setting*, FTC, <http://www.ftc.gov/speeches/ramirez/110621ssowkshp.pdf> (2011) (last visited Sept. 15, 2013).

²³⁷ *Id.*

²³⁸ Mark A. Lemly, *Intellectual Property Rights and Standard Setting Organizations*, 90 CAL. L. REV. 1889, 1899–1901 (2002).

²³⁹ *Id.*

²⁴⁰ James B. Koback, Jr., *Standard Setting, IP and Antitrust*, PRACTICING LAW INSTITUTE PATENTS, COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES, PLI Order No. 8816 (June 2006).

²⁴¹ Lemly, *supra* note 238, at 1899–1901.

²⁴² Upgrove, *supra* note 233.

²⁴³ *Id.*

this, each SSO establishes a set of rules addressing the intellectual property rights of members who have joined.²⁴⁴ 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.²⁴⁵ 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 SSO might address the problem of incentivizing the 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 could also 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.

1. 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 because the entities holding patent rights over certain technologies would gain access to the innovative thinking of an open-source community.²⁴⁶ For example, IBM has pledged several hundred patents to the open-source community in order to foster innovation:²⁴⁷

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

²⁴⁴ *Id.*

²⁴⁵ *Id.*

²⁴⁶ *See, e.g.*, Statement of Non-assertion of Named Patents Against OSS, IBM <http://www.ibm.com/ibm/licensing/patents/pledgedpatents.pdf> (last visited Feb. 12, 2012).

²⁴⁷ *Id.*

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.²⁴⁸

IBM likely is willing to donate patents because those patents are more valuable if used by the masses of an open-source community than languishing undeveloped by the company. Future value can be generated from the use of patented technology by a community, and companies like IBM can later capitalize on those technological advances. There is no reason to think that this perceived future value is limited to use with 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 convincing 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 the present value.²⁴⁹ 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.²⁵⁰ The terms of the Public Agreement create a risk for an entity that has invested large sums of money in obtaining a patent over valuable sequences of DNA because a competitor could theoretically sign its own BioBricks Public Agreement and then be able to infringe patent rights with impunity. By donating a valuable biological part to the BioBricks 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 BioBricks Foundation and a patent holder, in which it is agreed to allow the use of patented technology by BioBricks Foundation members, without actually signing the Contributor

²⁴⁸ *Id.*

²⁴⁹ 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).

²⁵⁰ See *The BioBrick Public Agreement*, *supra* note 80.

Agreement. This potential solution, 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. It is unlikely that members of the BioBricks Foundation would want to invest time developing a technology only to be forced to stop at some future date.

The establishment of a private SSO would create a medium through which the patented biological part could be given to BioBricks 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.

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

As discussed in Section V above,²⁵¹ one of the problems with using a contract licensing approach to maintaining openness in the BioBricks Foundation is that a party does not have any real recourse if another party violates the terms.²⁵² 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 strong declaration that a standard is being adopted will bring with it several aspects of protection that exist in common law.

One legal theory that exists in common law is equitable estoppel. Equitable estoppel is a legal principle that protects one party from

²⁵¹ *Supra* Part V.

²⁵² *See supra* Part V.

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another party's intentional, voluntary conduct.²⁵³ 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.²⁵⁴ First, the patent holder must lead the infringer, by misleading conduct, to reasonably infer that no property rights will be asserted.²⁵⁵ Types of misleading conduct include "specific statements, action, inaction, or silence where there was an obligation to speak."²⁵⁶ Second, the infringer must have relied on the misleading conduct of the patent holder.²⁵⁷ Third, the infringer must be materially prejudiced by allowing proceedings to continue.²⁵⁸

There is also case law demonstrating that when a patent holder induces another party to adopt a standard in the context of an SSO, the patent holder cannot arbitrarily enforce his or her rights at a later date.²⁵⁹ An example of this application of estoppel can be found in *Stambler v. Diebold, Inc.*²⁶⁰ In that case, the plaintiff allowed the American National Standards Institute (ANSI) to adopt, as an industry standard, a technology relating to card validation of ATM machines.²⁶¹ It was well known throughout the industry that the ANSI was considering adopting this standard, and it was also known that plaintiff held a patent on similar technology. Furthermore, the plaintiff sat on the ANSI committee, which adopted the standard.²⁶² Before official adoption, plaintiff had concluded that the proposed standard infringed his patent, but did not disclose this belief to other members of the committee.²⁶³ It was not until ten years later, when the standard was fully entrenched in ATM machine technology, that the plaintiff brought suit for patent infringement.²⁶⁴ Ultimately, Judge Platt 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 held

²⁵³ See BLACK'S LAW DICTIONARY, 253 (3d ed. 1996).

²⁵⁴ A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992).

²⁵⁵ *Id.*

²⁵⁶ *Id.*

²⁵⁷ *Id.*

²⁵⁸ *Id.* at 1028.

²⁵⁹ *Stambler v. Diebold, Inc.*, 11 U.S.P.Q.2d (BNA) 1709 (E.D.N.Y. 1988).

²⁶⁰ *Id.*

²⁶¹ *Id.* at 1713.

²⁶² *Id.*

²⁶³ *Id.*

²⁶⁴ *Id.*

that the conduct was intentional.²⁶⁵ The court used the theory of estoppel to deny the plaintiff the right to enforce the patent, reasoning that the plaintiff had a duty to speak out rather than allow the industry to adopt the standard.²⁶⁶ Judge Platt found it especially telling that the plaintiff had waited “while an entire industry implemented the proposed standard and then when the standards were adopted assert[ed] that his patent covered what manufacturers believed to be an open and available standard.”²⁶⁷

In light of the Federal Circuit’s three-part test and the holding of *Stambler v. Diebold*, the BioBricks Foundation could clearly be afforded the protection of estoppel for a biological part donated under a 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 BioBricks Foundation would be materially prejudiced by later enforcement because the Foundation would have built subsequent biological parts that are uniquely composable with the original donated part; *i.e.* the donated part is adopted as a standard. While all the elements of equitable estoppel might be available absent the formal adoption of any standards, the strong declaration that a SSO is adopting a standard makes fulfillment of the second and third prongs abundantly clear.

An alternative legal theory for preventing the assertion of patent rights over an adopted standard is that of an implied license.²⁶⁸ The primary difference between an implied license and equitable estoppel is that “that implied license looks for an affirmative grant of consent or permission to make, use, or sell.”²⁶⁹ Under this theory, the BioBricks Foundation would be protected from enforcement of patents that are acquired after a biological standard part has been adopted.²⁷⁰ An illustration of this type of protection can be found in *AMP Incorporated v. United States*. In that case, AMP entered into a

²⁶⁵ *Id.* at 1714.

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *AMP Inc. v. United States*, 389 F.2d 448 (Ct. Cl. 1968).

²⁶⁹ *Wang Labs., Inc. v. Mitsubishi Electronics of America, Inc.*, 103 F.3d 1571, 1581 (Fed. Cir. 1997)

²⁷⁰ *See AMP Inc.*, 389 F.2d at 449.

contract with the government to furnish “60 experimental models of [a] wire splicing tool.”²⁷¹ The contract granted the government “an irrevocable, non-exclusive, nontransferable and royalty-free” license to use the tool.²⁷² After AMP shipped the items, it discovered that its patent on the tool had been infringing another company’s patent.²⁷³ AMP purchased the rights to the other company’s patent and then tried to revoke the original license it granted the government.²⁷⁴ 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.²⁷⁵ The court reasoned that a license cannot be negated if there is no change in the structure of the invention.²⁷⁶

The holding of *AMP Incorporated* can be applied to biological parts adopted as a standard in an SSO setting. If an SSO member were to donate a biological part and subsequently acquire a patent on that part, an implied license would prevent the member from being able to enforce the after-acquired patent rights against BioBricks or any other members of the SSO. Furthermore, some courts have expanded the scope of implied license to include actions that fall short of express licenses.²⁷⁷ Thus, in the context of an SSO, when a biological part is formally adopted as a standard, it would indicate to members of the SSO that there is an implied license to use the part, based on the agreed upon terms.²⁷⁸

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

A standard setting organization creates a scenario where proprietary entities and open-source communities would have an aligned interest in the standard that is adopted. The patent holder benefits from an increased value of an adopted standard; the parties using the patented technology would benefit from the enhanced ability to innovate and collaborate through use of the standard. This

²⁷¹ *Id.*

²⁷² *Id.*

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ *AMP Inc.*, 389 F.2d at 448.

²⁷⁶ *Id.*

²⁷⁷ *See Wang Labs., Inc.*, 103 F.3d at 1582 .

²⁷⁸ *See id.* (The court looked to the entire course of conduct by the plaintiff, including the fact that they encouraged adoption of their technology as a standard, when concluding that an implied license defense was available).

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.²⁷⁹ For example, an SSO member that promotes the use of a patented technology, but later tries to enforce patent rights on unreasonable terms, could be sued under one of the legal theories described above.²⁸⁰ Unfortunately, this would require financial resources that the BioBricks Foundation does not have on its own. If, however, the interests of the other SSO members were aligned with that of the BioBricks Foundation, then a SSO member with money to spend could incidentally protect the interest of the BioBricks Foundation in trying to protect its own self-interest. Thus, the otherwise impracticable legal recourse of equitable estoppel and implied license becomes available to the BioBricks Foundation in the context of an SSO.

Also, the aligned interests of the BioBricks Foundation with the for-profit members of the SSO make it possible to address a problem regarding the establishment of a synthetic biology commons that no other previously proposed strategy could. Establishment of an SSO may help in getting finished, medically relevant products of BioBricks members out of the lab and into the clinic. For-profit biotechnology companies have the resources²⁸¹ and expertise available to undergo the arduous clinical trial process.²⁸² Also, clinical trials last many years, and the single entity of a corporation could stay focused on seeing the process through, without having to rely on any individual person to complete the process.²⁸³ These are endeavors that a synthetic biology commons could not achieve by its very nature, with

²⁷⁹ See Lemly, *supra* note 238 at 1899.

²⁸⁰ See *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992); *AMP Inc. v. United States*, 389 F.2d 448 (Ct. Cl. 1968).

²⁸¹ Avik Roy, *How the FDA Stifles New Cures, Part I: The Rising Cost of Clinical Trials*, FORBES (Apr. 24, 2012), <http://www.forbes.com/sites/aroy/2012/04/24/how-the-fda-stifles-new-cures-part-i-the-rising-cost-of-clinical-trials/> (“[A] recent total [of] R&D spending from the 12 leading pharmaceutical companies from 1997 to 2011. . . found that they had spent \$802 billion to gain approval for just 139 drugs: a staggering \$5.8 billion per drug.”)

²⁸² There are a host of regulations that govern the conduct of clinical trials involving both human and non-human animal subjects. See *FDA Regulations Relating to Good Clinical Practice and Clinical Trials*, FDA, <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm#FDARegulations> (last visited Sept. 16, 2013).

²⁸³ The time it takes to complete a clinical trial ranges from years to decades. See *Clinical Trials.gov*, <http://clinicaltrials.gov/show/NCT00249873> (last visited Sept. 16, 2013).

many individuals investing little time and money and producing something big with their aggregate work. Thus, with such an alignment of interests, the novel biological parts made by BioBricks 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, thereby 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.

VII. CONCLUSION

The emerging technology of synthetic biology promises to have a huge impact on industry and medicine.²⁸⁴ 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,²⁸⁵ 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 of the problems associated with an open-source approach to synthetic biology and the 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. Here, a novel SSO approach is proposed that not only could maintain openness, but also motivate donation of synthetic biological parts and help bring biomedical advances closer to clinical trials. The stated goal of the BioBricks Foundation is to “accelerate the pace of innovation, collapse development timelines and speed time-to-market of inventive synthetic biology-based solutions.”²⁸⁶ Private SSOs have achieved these same ends with various other technologies.²⁸⁷ Thus, even though the BioBricks Foundation strategy for advancing synthetic biology involves largely open-source principles, the establishment of a formal private SSO may better advance the Foundation’s goals. In a world where intellectual property rights over foundational technologies threaten

²⁸⁴ Brent Erickson et al., *Synthetic Biology: Regulating Industry Uses of New Biotechnologies*, 333 SCIENCE 1254 (2011).

²⁸⁵ Kean, *supra*, note 57, at 531 (2011).

²⁸⁶ *The SBx.0 Series*, BIOBRICKS, <http://sb5.biobricks.org/files/BioBricksSB5flyer-v2.pdf> (last visited June 4, 2013).

²⁸⁷ Upgrove, *supra* note 233.

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