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Open Source Business Models and Synthetic Biology

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OPEN SOURCE BUSINESS MODELS AND SYNTHETIC BIOLOGY

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ABSTRACT

The software industry has successfully utilized open source business models namely with software such as Android and Linux. Open source business models allow individuals to collaborate and share information without fear that the shared information will be commercially misused. Given the similarities between software source code and genetic sequences, innovators in the field of synthetic biology feel that open source business models can help further innovation for synthetic biology in a similar manner. However, when determining whether to join an open source project, practitioners must first identify if such a project will be beneficial to their goals. This Comment discuss benefits and risks associated with open source business models as applied to synthetic biology, as well as possible solutions to some of the risks identified. This Comment concludes with possible suggestions to solve some of the issues associated with open source business models with the goal to further current open source initiatives.

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I. INTRODUCTION

Synthetic biology, "the synthesis of unnatural organic molecules that function in living systems," is a rapidly emerging scientific discipline with numerous important industrial applications.[1] Synthetic biology applies to the fields of medicine, especially identifying and repairing genetically damaged cells; agriculture, particularly genetically modified produce; and industrial technology, namely biofuels.[2] Advances in synthetic biology have the potential to benefit humanity in a myriad of ways.[3]

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1. Steven A. Benner & A. Michael Sismour, *Synthetic Biology*, 6 NATURE REVIEWS GENETICS 533, 533 (2005).

2. Arti Rai & James Boyle, *Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons*, 5 PLOS BIOLOGY 389, 389 (2007).

3. *Id.*

As with most other research fields, synthetic biology companies frequently patent their inventions.[4] However, synthetic biology has been problematic. Specifically, courts have not clearly defined nonobviousness in the field of biosynthesis,[5] nor has the U.S. Patent & Trademark Office (USPTO) and the courts rigorously applied the enablement and written description doctrines to the field of synthetic biology.[6] These inadequacies have resulted in synthetic biology patents that are overly broad and often cover basic components or parts of numerous synthetic biology products.[7] Such patents hinder new and important innovations by limiting the use of basic parts.[8] One possible solution to this problem could be the integration of open source business models to synthetic biology.[9]

Software companies have successfully used open source business models; for example, the Linux operating system.[10] However, the synthetic biology field has only recently considered open source approaches.[11] Given the success of open source software, proponents of the business model analogize synthetic biology to software and urge innovators to adapt a similar business model.[12] Like computer engineers, synthetic biologists also use multiple parts when working on a new product.[13] "The hope is that an open-source synthetic biology commons would encourage innovation in ways similar to the wildly successful open-source software movement."[14] However, open source business practices have "thus far failed to make much impact on the field of [synthetic] biology."[15]

4. Andrew W. Torrance, *DNA Copyright*, 46 VAL. U. L. REV. 1, 15–16 (2011).

5. Andrew W. Torrance & Linda J. Kahl, *Bringing Standards to Life: Synthetic Biology Standards and Intellectual Property*, 30 SANTA CLARA HIGH TECH. L.J. 199, 203 (2014); Brandon Smith, *The Patentability of Human Embryonic Stem Cells in Light of Myriad*, 96 J. PAT. & TRADEMARK OFF. SOC'Y 112, 113 (2014) ("[i]n the last five years, the Court has changed the landscape of patentable subject matter several times.").

6. Torrance & Kahl, *supra* note 5, at 203.

7. Rai & Boyle, *supra* note 2, at 390–91; *see also* Smith, *supra* note 5, at 116 ("[a] patent thicket would drastically decrease biotechnology companies' freedom to operate.").

8. *See* Torrance & Kahl, *supra* note 5, at 203. "In theory, negative effects caused by patent rights covering commonly used components or methods in synthetic biology could be exacerbated if those patented components or methods were to be adopted as standards."

9. *See infra* Part IV.B.

10. Joachim Henkel & Stephen Maurer, *The Economics of Synthetic Biology*, MOLECULAR SYSTEMS BIOLOGY, June 2007, at 1; Jerry Hirsch & Tiffany Hsu, *Elon Musk opens up Tesla patents to everyone*, LA TIMES (June 12, 2014, 6:28 PM), http://www.latimes.com/business/autos/la-fi-tesla-open-source-20140613-story.html#page=1. "The open-source software movement has evolved over the last four decades, giving rise to systems such as the Linux operating system and the Mozilla Firefox Web browser, which can be freely customized and distributed."

11. Stephen Maurer, *Before it's Too Late*, 10 EUR. MOLECULAR BIOLOGY ORG. REP. 806, 806 (2009).

12. *Id.*

13. A part, for the purposes of this paper and relative to synthetic biology, is essentially the genetic sequence or data that is used to create a basic component of an artificial biological system.

14. Ethan R. Fitzpatrick, *Open Source Synthetic Biology: Problems and Solutions*, 43 SETON HALL L. REV. 1363, 1364 (2013).

15. Torrance, *supra* note 4, at 39.

This Comment analyzes the costs and benefits of the open source business model and its applicability to synthetic biology, alternative forms of legal protection for synthetic biology, and possible implementation strategies of an open source business model to synthetic biology. Benefits of an open source strategy include shared research and development costs, better and more reliable parts, better and cheaper final products, and a variety of personal incentives.[16] Some personal incentives regard one's own reputation, impressing potential employers, and learning new skills.[17] However, some risks associated with open source business strategies include a lack of financial incentives, limited protections for sharing work, and limited incentives to entice other entities to participate in an open source project.[18] Furthermore, the benefits of a patent and the protections provided by patents still appeal to many companies, further preventing them from joining open source initiatives.[19] Of these risks, this Comment will argue that the greatest deterrent to open source projects is the lack of intellectual property protections for genetic sequences.[20] Thus, this Comment argues that more entities would be willing to participate in open source projects if copyright law extended to and protected genetic sequences.[21] As copyright protections are currently not available to genetic sequences, copyright licenses may be a viable alternative to help protect shared information.[22] Further, this Comment discusses other possible remedies that will entice others to join open source initiatives.[23] For example, government incentives may help others join open source projects.[24]

This comments proceeds as follows. Part II provides background information on synthetic biology, open source business models, and examples of current companies that have begun to implement an open source business model. Part III discusses current legal issues in the field synthetic biology for innovators. Part IV analyzes the application of an open source business model to synthetic biology including the benefits and the costs or risks of open source strategies. Part V presents possible solutions to the legal and non-legal issues associated with synthetic biology. Part VI discusses actions that the government, congress, USPTO, and the Courts can take to help further open source initiatives, and the conclusion follows.

II. WHAT IS SYNTHETIC BIOLOGY?

The definition of synthetic biology varies depending on one's technical

16. *See infra* Part IV.D.
17. *See infra* notes 197–99 and accompanying text.
18. *See infra* Part IV.E.
19. *See infra* Parts III.A., IV.E.
20. *See infra* Part IV.F.
21. *See infra* Part V.A.
22. *See infra* Part V.B.
23. *See infra* Parts V.C., VI.
24. *See infra* Part VI.

background.[25] Ethan Fitzpatrick summarized how different practitioners define "synthetic biology" in his article *Open Source Synthetic Biology: Problems and Solutions*:

> [F]or 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.' 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. . .' 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.'[26]

Regardless of the technical background, synthetic biology essentially encompasses all aspects of research regarding genetic material.[27] *Synthetic organisms* produced by synthetic biologists have medical applications and "a large variety of industrial" applications.[28] Synthetic biologists are also exploring the "possibility of low-cost production of 'green' fuels such as cellulosic ethanol" as an alternative to current damaging fuels for both vehicles and electrical power.[29]

To summarize genetics in a sentence, famous geneticist Francis Crick stated, "DNA makes RNA, RNA makes protein, and proteins make us."[30] DNA—deoxyribonucleic acid—holds all of an organism's genetic data.[31] DNA is composed of nucleotides—A, G, C, T.[32] Rearrangements of these four biochemical compounds are responsible for all the complexity and diversity of living organisms on the planet.[33] Each cell in the human body contains an entire blueprint of highly condensed sequences of this genomic data.[34] Differential gene expression through transcription and translation allow the body to specify the construction of specific cells in specific locations, thus preventing mistakes like the development of cardiovascular cells in the digestive tract.[35] Although different cells in the body have the same DNA, different genes are

25. Fitzpatrick, *supra* note 14, at 1367.
26. *Id.* (quoting Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449, 449 (2005)).
27. Fitzpatrick, *supra* note 14, at 1367.
28. Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 Tex. L. Rev. 1745, 1746 (2007).
29. *Id.*
30. Torrance, *supra* note 4, at 13.
31. Benner & Sismour, *supra* note 1, at 534.
32. *Id.*
33. *Id.*
34. *See* CHRISTOPHER K. MATHEWS ET AL., BIOCHEMISTRY, 90–129 (4th ed. 2012).
35. *Id.*

activated or expressed in different cells, which is necessary for the cells to perform and function properly.[36] The process of transcription is the first step in the tangible realization of genetic information.[37] In this process, DNA is rewritten as complementary RNA strands.[38]

RNA is composed of A, G, C nucleotides as well, but a U nucleotide is present rather than the T nucleotide.[39] The transcription process of DNA to RNA allows for highly diverse manipulations of our genetic information.[40] This process allows the genetic data stored on our forty-six chromosomes to become even more diverse and expands its potential for unique arrangements of information.[41] Once the DNA is transcribed to RNA, the next step is translation of RNA to amino acids. There are twenty amino acids in the human body, and these biochemical compounds are the basic building blocks for all the proteins and enzymes in animals.[42] Thus, at this point, genetic information becomes a tangible protein or enzyme that performs a vital biochemical function in the body.[43]

Researchers realize that manipulations of the basic underlying genetic coding in an organism results in changes in the physical structures and functions of that organisms' cells.[44] As such, synthetic biologists use these nucleotides to create modified DNA strands that could have many different purposes. For example, synthetic biologist may create a genetically modified strand of carrot DNA that would make the carrot grow bigger and faster.[45] By manipulating the genetic code responsible for dictating the growth of the

36. RUSSELL KORBKIN, STEM CELL CENTURY: LAW AND POLICY FOR A BREAKTHROUGH TECHNOLOGY 7 (2007). This information is extremely important for stem cell research. *Id.* Stem cells have the ability to differentiate between different types of cells based on gene expression. *Id.* Stem cell research is extremely important for advancements in the field of synthetic biology.

37. CHRISTOPHER K. MATHEWS ET AL., BIOCHEMISTRY, 90–129 (4th ed. 2012).

38. *Id.*

39. *Id.*

40. *Id.*; Heidi Ledford, *Bioengineers look Beyond Patents*, 499 NATURE 16, 16 (2013), http://www.nature.com/polopoly_fs/1.13320!/menu/main/topColumns/topLeftColumn/pdf/499016a.pdf. "Synthetic biologists aim to bring engineering principles to bear on genetic manipulation," and advancements in the field of synthetic biology are directly related to the ability to manipulate genetic data.); *see also* Mauricio Rojas et al., *Genetic engineering of proteins with cell membrane permeability*, 16 NATURE BIOTECHNOLOGY 370, 374 (1998) ("[G]reat effort has been made to develop various methods of enhancing intracellular levels of specific proteins" for medical purposes and for a variety of researching purposes.

41. CHRISTOPHER K. MATHEWS ET AL., BIOCHEMISTRY, 90–129 (4th ed. 2012).

42. *Id.*

43. *Id.*

44. *See* Sherret S. Chase, *Anti-Famine Strategy: Genetic Engineering for Food*, 25 BULL. ATOMIC SCIENTISTS 2, 2–6 (1969); Michael J. Mann et al., *Genetic engineering of vein grafts resistant to atherosclerosis*, 92 PROC. NATL. ACAD. SCI 4502, 4502 (May 1995). For example, "researchers have speculated that genetic engineering can improve the long-term function of vascular grafts which are prone to atherosclerosis and occlusion." Findings show that "an intraoperative gene therapy approach using antisense oligodeoxynucleotide blockage of medial smooth muscle cell proliferation can prevent the accelerated atherosclerosis that is responsible for autologous vein graft failure."

45. *See* Chase, *supra* note 44, at 2–6.

carrot, scientists can essentially program their own coding that will increase the cellular rates of development in the carrot cells.[46] This type of genetic engineering has led to short-stemmed wheat crops by engineering the plants with the Norin 10 gene, resulting in crops yielding more harvestable grain.[47] Similarly, attempts to maximize yield of crops have led to solving the problem of crop destruction from "disease and insects" and improving the "nutritive quality" of certain foods to incorporate necessary amino acids.[48] The advent of "artificial DNA cutters" and other designed molecular tools make these genetic engineer feats feasible.[49]

Likewise, synthetic biologist identify genes that serve specific functions to help fight diseases or that cause diseases. For example, synthetic biologist can identify the "gene products that enhance the ability of macrophages" that kill tubercle bacilli.[50] This information would be vital to finding and increasing resistance to *M. tuberculosis*.[51] Studying genetics and identifying genetic sequences can be key in fighting many diseases.

Scientists can write their own sequences of nucleotides and specify exactly which genes to manipulate within the coding of a particular organism.[52] Essentially, especially in the field of agriculture and medicine, synthetic biologists strive "to make genetic engineering faster and easier."[53] The invention and application of next-generation DNA and RNA sequencing to genetic engineering has increased the possibilities of creating more useful and specialized medical pharmaceuticals.[54] This technology has made it possible to sequence millions of DNA nucleotides accurately and efficiently in a matter of days.[55] Access to a set of previously modified genetic sequences in the public domain would allow synthetic biologists to work more efficiently and would give scientists further flexibility in future innovations.[56]

46. *Id.*

47. *Id.*; Larry L. Green, *Antibody engineering via genetic engineering of the mouse: XenoMouse strains are a vehicle for the facile generation of therapeutic human monoclonal antibodies*, 231 J. IMMUNOLOGICAL METHODS 11, 20 (1999). Just as plants can be engineered, animals can be genetically modified and can be thus used to conduct genetic research for medical purposes. "By using XenoMouse animals and genetically engineering large portions of "thenative human Ig loci into the mouse germlin," researchers were able to find that "with the human Ig transgenes functionally replacing their murine counterparts, XenoMouse animals utilize the natural ability of the murine immune system to create high affinity human antibodies."

48. *See* Chase, *supra* note 44, at 2–6.

49. *Id.*

50. William W. Stead, MD, *Genetics and Resistance to Tuberculosis, Could Resistance be enhanced by genetic engineering?*, 116 ANNALS OF INTERNAL MED. 937, 940 (1992).

51. *Id*.

52. *See* Chase, *supra* note 44, at 2–6.

53. Fitzpatrick, *supra* note 14, at 1368.

54. *See* Chase, *supra* note 44, at 2–6.

55. *Id.*

56. Maurer, *supra* note 11, at 806.

III. CURRENT PATENT SYSTEM FOR SYNTHETIC BIOLOGY

A. Benefits of Patents

Currently, the patent system is the "on the forefront of controversies."[57] Although this Comment focuses on the issues with the patent system in relation to synthetic biology, the patent system has many benefits. When an inventor creates a new technology, patent protection allows the inventor to share his invention to benefit society and allows the inventor to have property rights on his invention.[58] Patents create incentives for inventors to invent as patent law confers an "exclusive right to make, use, or sell the invention for a twenty-year period."[59] Patents are extremely important for pharmaceuticals; pharmaceuticals require regulatory approval before marketing can begin and patents prevent generic companies from entering the market.[60] Even though patents give inventors exclusive rights, "there is little or no reward to the inventor unless buyers" are interested in the innovation.[61] In essence, the patent system ensures that "incentives are directed towards generating products that people want" while protecting the innovator of that product.[62]

B. Issues With Patents

The patent system is not without its faults. Innovators in the field of synthetic biology encounter a variety of legal roadblocks in their research due to patents. To begin, basic and obvious information may be covered under broad patents—which thereby hinders that information from being used for a different patent that might be more complex and useful. New technologies are "especially vulnerable to broad patents that suppress innovation."[63] Furthermore, basic manufacturing methods and process are susceptible to patents. When the patent covers basic methods of process, innovators must either pay licensing fees to use that method or figure out a new way to achieve the a similar result.[64] Both of these alternatives can be costly and inefficient for the innovator.

57. Daniel Gifford, *How do the Social Benefits and Costs of the Patent System Stack up in Pharmaceuticals?*, 12 J. INTELL. PROP. L. 75, 78 (2004).

58. *Id.* at 81.

59. *Id.*

60. *Id.*; Josh Bloom, *Should Patents on Pharmaceuticals be Extended to Encourage Innovation?*, WALL ST. J. 1 (2012), http://twileshare.com/uploads/_Should_Patents_on_Pharmaceuticals_Be_Extended_to_Encourage_Innovation.pdf ([p]atents are extremely beneficial to the pharmaceutical industry. In fact, the profits made during the scope of a patent funds "research that produces breakthrough treatments. Many argue that patents should be extended for pharmaceutical companies because "[i]nnovation [d]emands [i]t").

61. Gifford, *supra* note 57, at 82.

62. *Id.*

63. Fitzpatrick, *supra* note 14, at 1371.

64. *Frequently Asked Questions*, BIOBRICK FOUND., https://biobricks.org/bpa/faq/#1 (last visited Sept. 9, 2014).

Another issue with patents concerns foundational patents. Foundational patents are "patents with broad claims that appeared important to a large percentage of work in the area."[65] Foundational patents are problematic because foundational patents slow research and impede technology growth in the industry.[66] Because patents are granted subjectively and the Federal Circuit has a low nonobviousness threshold in the area of genetics, foundational patents are likely to be granted.[67] Currently, the Federal Circuit has a problematic way to determine obviousness.[68] Rather than applying what is nonobvious to a practicing synthetic biologist, the courts focus on the "rules about nonobvious developed for chemical inventions in the mid-twentieth century."[69] The United States Patent Office (USPTO) has also "failed to properly apply 'nonobvious' in the fields of biotechnology."[70] Practitioners fear that that same level of "nonobvious" will extend to synthetic biology, which would result in patents for foundational and basic parts.[71] In fact, broad patents are already present "in the field of synthetic biology."[72] Researchers and practitioners fear that foundational patents "will stifle the development of synthetic biology along with all of its potential benefits."[73] In fact, such patents are already often "used to halt research, prevent medical testing, and keep vital information from" patients and doctors.[74]

Even narrow patents can be problematic. Another major issue with the patent system is patent thickets. A patent thicket is an "overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees."[75] Patent thickets occur when differ-

65. Kumar & Rai, *supra* note 28, at 1751; M.A. Heller & R.S. Eisenberg, *Can Patents Deter Innovation?The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998), http://www.sciencemag.org/content/280/5364/698.full.pdf ([b]road patents that cover basic aspects of "nanotechnology — such as quantum dots, nanowires and fullerenes, carbon nanotubes and methods for making them — hamper conscientious innovators, who must spend time and money to acquire" licenses to utilize those parts to avoid lawsuits)

66. Kumar & Rai, *supra* note 28, at 1753; *but see* M. A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 601 (2005) (noting that "computing software grew up without overzealous patenting hindering innovation.").

67. Kumar & Rai, *supra* note 28, at 1753.

68. *Id.* at 1749; *see* Smith, *supra* note 5, at 113 ("[i]n the last five years, the Court has changed the landscape of patentable subject matter several times").

69. Kumar & Rai, *supra* note 28, at 1749.

70. Rai & Boyle, *supra* note 2, at 390.

71. *Id.*

72. *Id.*

73. Fitzpatrick, *supra* note 14, at 1371; *see also* Heller & Eisenberg, *supra* note 65, at 698.

74. Torrance, *supra* note 4, at 17.

75. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POLICY AND THE ECONOMY 119, 119 (2001); Joshua M. Pearce, *Make nanotechnology research open-source*, 491 NATURE 519, 519 (2012), http://www.nature.com/nature/journal/v491/n7425/full/491519a.html ("[a]ny innovator wishing to work on or sell products based on single-walled carbon nanotubes in the United States must wade through more than 1,600 US patent" and then obtain multiple licenses to use any much of the basic and foundational information covered in those patents).

ent small bits of technology, such as computer data chips, are necessary to create a final product, such as a computer. Patent thickets pose issues for synthetic biologists, as with software engineers, because most final products utilize multiple parts, which may be patented.[76] For example, the number of patent applications for stem cells has been growing.[77] Scientists fear that patent thickets in stem cell technology would drastically decrease biotechnology companies' ability to innovate.[78]

Patents essentially provide a monopoly on the innovation that has a patent.[79] The innovation itself may be inferior, but it is the only product on the market for the duration of that monopoly.[80] Furthermore, patents cost a lot of money and time.[81] To get a patent, the innovator must pay attorney fees, wait for USPTO to approve the patent, and then pay maintenance fees on top of that to keep the patent. Simply put, "obtaining a patent is expensive—approximately $10,000 in the US."[82]

Therefore, there are many reasons why a company, particularly a small business or academic facility, would look at the patent system unfavorably. Patents often cover basic information, basic methods or processes, fundamental technologies, and patents are extremely expensive. However, besides patents, innovators cannot seek any other types of intellectual property rights.[83] The biggest legal hurdle that synthetic biologist face but software engineers do not "is that gene data—unlike software—cannot be copyrighted."[84]

C. Issues from recent Supreme Court Cases

Case law concerning patentability of synthetic biology is murky at best.[85] The courts and the USPTO have yet to define nonobvious and proper patentable subject matter for synthetic biology related patents.[86] However, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Court held that

76. Kumar & Rai, *supra* note 28, at 1757; *see* Pearce, *supra* note 76, at 519 (patent thickets hinder nanotechnology. "Excessive patenting is increasing costs, slowing technical development[,] and removing from the public domain fundamental knowledge about the understanding and control of matter on the atomic or molecular scale.").

77. Smith, *supra* note 5, at 116.

78. *Id.*

79. Henkel & Maurer, *supra* note 10, at 2.

80. *Id.*

81. *Frequently Asked Questions*, *supra* note 64.

82. Maurer, *supra* note 11, at 808; Smith, *supra* note 5, at 113 ("in 1874, the Court held that purified paper pulp cellulose was not patentable subject matter, yet the Court ruled in 1980 that a genetically modified bacterium was patentable subject matter.); *see* American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566, 594-607 (1874); *see* Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980).

83. Maurer, *supra* note 11, at 808; Smith, *supra* note 5, at 113 ("in the last five years, the Court has changed the landscape of patentable subject matter several times.").

84. Maurer, *supra* note 11, at 808.

85. Rai & Boyle, *supra* note 2, at 390.

86. *Id.*

natural DNA is not patentable.[87] In *Myriad*, Myriad Genetics, Inc. discovered the location and sequence of two naturally occurring human genes—BRCA1 and BRCA2.[88] These genes are associated with breast and ovarian cancer, and mutations in these genes can help identify individuals more likely to have such cancers.[89] After discovering the location and sequences of the genes, Myriad sought and obtained a number of patents with multiple claims.[90] If valid, the patents would give Myriad "exclusive right to isolate" and create an individual's BRCA1 and BRCA2 genes.[91] The University of Pennsylvania's Genetic Diagnostic Laboratory (GDL) and Dr. Ostrer also conducted similar genetic testing services to women.[92] Myraid responded with letters asserting patent infringement forcing GDL and Dr. Ostrer to cease sequencing.[93]

Some years later, Dr. Ostrer and others filed a lawsuit seeking a declaration that Myriad's patents were invalid.[94] Although the District Court held that the claims were invalid because the patented genes were naturally occurring, the Federal Circuit reversed and held that the isolated genetic materials were patent eligible under 35 U.S.C. § 101.[95] The issue in dispute was whether "separating a specific gene or sequence of nucleotides from the rest of the chromosome" was enough to grant the first individual to isolate that sequence a patent.[96] The Supreme Court granted certiorari and held that patents cannot claim naturally occurring phenomena.[97]

In their decision, the Court relied on *Diamond v Chakrabarty*.[98] In *Chakrabarty*, scientists modified bacterium by adding plasmids to the bacterium—which enabled it to break down crude oil.[99] The Court in *Chakrabarty* held that the modified bacterium was patentable because it was not a "natural phenomenon" but instead "a product of human ingenuity with a distinctive name, character [and] use."[100] By contrast, the BRCA genes discovered in *Myriad* were naturally occurring, and Myriad did not add anything to those genes.[101] The Court in *Myriad* held that "separating [a] gene from its sur-

87. 133 S. Ct. 2107, 2117 (2013).
88. *Id.* at 2112.
89. *Id.*
90. *Id.* at 2113.
91. *Id.*
92. *Id.* at 2114.
93. *Id.*
94. *Id.*
95. *Id.*; 35 U.S.C. § 101 (2014) provides that "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."
96. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2114.
97. *Id.*
98. *Id.* at 2116.
99. Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).
100. *Id.* at 309–10 (internal quotations omitted).
101. *Ass'n for Molecular Pathology,* 133 S. Ct. at 2117.

rounding genetic material is not an act of invention."[102]

One of Myriad's arguments exemplifies the problem with the USPTO; Myriad argued that its patent should not be invalidated because the USPTO had a history of awarding gene patents.[103] Myriad's argument illustrates the contention that the USPTO does not have specific guidelines for determining patentability, and the Courts have yet to resolve this issue. Although *Myriad* resolved some issues of what is patent-eligible, neither congress nor the USPTO have defined what is nonobvious.

The Court in *Myriad* further held that the ruling did not extend to methods or new applications involving knowledge of the BRCA genes.[104] Furthermore, the Court added that modified DNA is still patentable.[105] *Myriad* by far has been the most significant decision in the field of synthetic biology. Before the ruling, patent prosecutors would routinely file patents after isolating genetic sequences.[106] The decision, however, still allows synthetic biologists to seek patents on modified genetic data. *Myriad* merely excludes scientists and patent prosecutors from seeking patents on genetic data that is present in nature, even if it is extremely difficult to isolate.[107]

Case law regarding intellectual property protections for software has been similarly unclear. In June 2014, the United States Supreme Court in *Alice Corp.* held that otherwise patent-illegible abstract ideas cannot be patented if the claim merely tries to apply that idea with a computer.[108] The Court discussed *Myriad Genetics* and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* in its ruling. The analysis of these cases is of particular interest given that both cases concern synthetic biology while *Alice Corp* concerns software.

In *Mayo*, the claims concerned the processes that helped doctors determine the proper dosage of a thiopurine drug used to treat patients with autoimmune diseases.[109] The claims essentially applied natural laws describing the relationship between the concentration of certain tiopurine metabolites in the blood and the effects the drug would have on the person based on those concentrations.[110] The issue was whether the claimed processes transformed "unpatentable natural laws into patent eligible applications of those laws."[111] The Court held that those claims did not and thus the processes

102. *Id.*

103. *Id.* at 2118; *see also* J.E.M Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 125 (2001).

104. *Ass'n for Molecular Pathology,* 133 S. Ct. at 2118.

105. *Id.*

106. *See* Torrance, *supra* note 4, at 17 ("approximately 20% of known genes in the human genome have been claimed in patents issued by the" USPTO based on information available in 2005).

107. *Ass'n for Molecular Pathology,* 133 S. Ct. at 2118.

108. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2349 (2014).

109. Mayo Collaborative Serv. v. Prometheus Labs, Inc., 132 S. Ct. 1289, 1294 (2012).

110. *Id.*

111. *Id.*

were not patentable.[112]

The Court in *Alice Corp* applied the two-part test from *Mayo* to the software claims at issue; the Court first examined the claim to determine whether the claims at issue regarded a patent-ineligible concept and then whether it contained an "inventive concept" sufficient to "transform" the claimed abstract idea into a patent-eligible application.[113] The Court held that the method claims—which simply required generic computer implementation—failed to transform the abstract idea of intermediated settlement into a patent eligible invention.[114]

Given the similarities between software and synthetic biology, the courts may soon expand software law to the realm of synthetic biology. The analysis used in the case law discussed illustrates that the Court was willing to extend its analysis for patent eligibility from one technical field to another. However, another issue is what the Court will find to be patent ineligible next.[115] Based on the uncertainty and limits on patentability, companies may soon explore open source business models for their companies to avoid any legal issues created by the recent case law.[116]

IV. OPEN SOURCE BUSINESS MODEL FOR SYNTHETIC BIOLOGY

Although an open source business model for synthetic biology may work, there is no guarantee.[117] Compared to the software industry, biology research has not exploited the power of shared, standardized components, but that is changing.[118] Open source business models have both costs and benefits—which must be thoroughly analyzed before concluding that synthetic biologists should immediately implement open source business strategies.

A. What is Open Source?

The term "open source" refers to information that "can be modified because its design is publicly accessible."[119] Open source models are most commonly associated with software.[120] When a software producer decides to implement an open source business model, they "make their source code

112. *Id.*

113. *Alice Corp.*, 134 S. Ct. at 2355.

114. *Id.* at 2357.

115. *See* Torrance & Kahl, *supra* note 5, at 203 ("[i]n practice, the past few years have seen tremendous flux in how courts interpret the patent-eligibility of both methods, such as diagnostic tests, and components, such as isolated DNA molecules, essential to synthetic biology.").

116. *Id.*

117. *See* Stephen M. Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 6 MINN. J.L. SCI. & TECH. 169, 172 (2004).

118. Henkel & Maurer, *supra* note 10, at 1.

119. *See What is Open Source?*, OPENSOURCE.COM, http://opensource.com/resources/what-open-source (last visited Mar. 24, 2015).).

120. *Id.*

freely available for improvement, modification, and redistribution."[121] These producers believe that profits realized through "software services and support (rather than for the software itself) is more lucrative."[122]

Open source software has many advantages. First, "[o]pen source software comes free of license fees."[123] In other words, this means that the buyer pays less for the software, and sometimes the software is available at no cost.[124] Second, the software can be easily modified to meet "the customer's needs."[125] Because the software code is available, anyone can modify the code to meet a specific consumer need.[126] Accordingly, users can quickly identify and fix bugs in the software or build enhancements for the software based on consumer needs.[127] Proprietary software, on the other hand, is improved and fixed depending on the "motivation and resources of the software developer" rather than by need of the user.[128] Third, the software has a "worldwide audience" due to its low costs.[129] In other words, because there are minimal fees to get the software, everyone around the world theoretically can access the software regardless of their economic status.[130]

However, open source software also has its disadvantages. First, because the software is open source and the source code is available to everyone, any software "products derived from the source code" must also be available freely.[131] Thus, software producers are "constrained to give away the fruits of their labor."[132] Second, due to a lack of funding, open source pro-

121. Rai & Boyle, *supra* note 2, at 391; *see also* Jason C. Goldwater et al., *The Use of Open Source Electronic Health Records within the Federal Safety Net*, 21 J. AM. MED. INFO. ASS'N 280, 280 (2014) ("[b]ecause the source code is freely available to all potential users, open source software development is more flexible and transparent than other processes and, therefore, encourages a practice of collaboration among developers and users of the software.").

122. *See What is Open Source?*, *supra* note 119.

123. Bennett M. Sigmond, *Free/Open Source Software Licensing–Too Big to Ignore*, 34 COLO. LAW. 89, 90 (2005).

124. *Id.*

125. *Id.*

126. *See* Goldwater et al., *supra* note 121, at 280 ("[t]he open source community promotes sharing, enhancing and adding applications to the base source code, and provides an avenue to release modified versions of the application for the benefit of the user community as a whole.").

127. *See* Sigmond, *supra* note 123, at 90; Quentin Hardy, *Open source and the Challenge of Making Money*, BITS (July 23, 2014, 2:28 PM), http://bits.blogs.nytimes.com/2014/07/23/open-source-and-the-challenge-of-making-money/?_r=2. ("[h]aving many people in many places working on something. . . is a way to experiment with a lot of possibilities, make a lot of mistakes quickly, figure out what works faster.").

128. Sigmond, *supra* note 123, at 90.

129. *Id.*

130. Goldwater et al., *supra* note 121, at 280 ([o]pen source is defined as the "ability to copy, modify, use[,] and distribute software source code" and is thus freely available to all potential users).

131. Sigmond, *supra* note 123, at 90.

132. *Id.;* Hardy, *supra* note 127. Because everything is given away for free essentially, open source business models raise the "question of whether it makes sense to build free stuff at all." Many who have used the open source strategy are not fond of it from a business perspective.

jects are often abandoned.[133] Finally, because open source software often is developed on a volunteer basis, there is no assurance that upgrades or bug fixes will be built at all.[134]

The most popular success story of open source software is the Linux. At first, Linux was only a project that Linus Torvalds decided to create just for fun.[135] However, the software attracted the attention of other programmers, and programmers combined Linux with other open source software tools.[136] Soon enough, Linux become a serious operating system and has a license under the General Public License ("GPL").[137] The Linux Foundation now fosters open source collaborative projects throughout the software industry. Linux Foundation holds that people working together can use Linux to "solve harder problems, innovate faster than ever, and change the way the world works together."[138] Essentially, Linus Torvaldus sparked an open source Revolution when he created Linux.[139]

B. Why Open Source for Synthetic Biology?

An open source business model could benefit the field of synthetic biology as it has in the computer software industry.[140] Computer software and synthetic biology share many similarities that are readily apparent when comparing "strings of DNA bases" to software source code.[141] In the same way that programmers find bugs and write patches, biologists look for proteins ("targets") and select chemicals ("drug candidates") that bind to them and affect their behavior in desirable ways.[142] Likewise, many argue that an open parts theory, which has benefited software in the past, would also help

133. Sigmond, *supra* note 123, at 90.

134. *Id.*; *see also* Goldwater et al., *supra* note 121, at 280 (in addition to the limited volunteers that may work on an open source project, only a small number of the suggested changes to the source code are even incorporated).

135. *About Us*, LINUX FOUNDATION, http://www.linuxfoundation.org/about (last visited Mar. 24, 2015).

136. Sigmond, *supra* note 123, at 90; Goldwater et al., *supra* note 121, at 280 (although a "substantial number of developers refined and contributed changes to the source code, only a number of these suggested changes are incorporated into" the actual Linux software).

137. *About us*, *supra* note 135.

138. *Id.*

139. *Id.*

140. *See* Ashlee Vance, *Open Source as a Model for Business Is Elusive*, N.Y. TIMES, (November 29, 2009), www.nytimes.com/2009/11/30/technology/business-computing/30open.html?adxnnl=1&pagewanted=all&adxnnlx=1427209375-WiT7B0umKeYH7c7meQhnzA. "The best-known open-source company is Red Hat, which produces a variant of the Linux operating system for server computers. Like most of its peers, Red Hat offers a free version of its base product and relies on selling support services and extra tools for revenue. In its last fiscal year, which ended in March, the company's revenue rose 25 percent to $653 million, and it reported net income of $79 million.")

141. Rai & Boyle, *supra* note 2, at 391.

142. Maurer et al., *supra* note 117, at 171.

advance research in synthetic biology.[143]

In the software industry, complex computer chips and software are made up of multiple smaller parts.[144] Often, many of these parts come from open source libraries.[145] Similarly, biological systems are comprised of multiple parts.[146] For example, Amyris Biotechnology synthesized yeast and bacteria with multiple parts so that it could synthesize a drug called artemisinin.[147] Access to multiple parts would enable synthetic biologists to make biological systems—like complex software—more efficiently.[148]

The idea for an open source business model for synthetic biology has been around since the emergence of the field.[149] Proponents of such a business model "imagine a world in which academic researchers and companies who develop DNA parts share them freely with one [an]other to advance the whole field."[150] Currently, however, "developers use patent protection and secrecy to hoard the best parts or otherwise charge others to use them."[151] The key to a successful open source business model for synthetic biology would be to "create libraries of standard gene sequences ('parts') that reliably perform simple functions like encoding an enzyme or building a protein that detects light."[152] Furthermore, these modular parts—which are termed "standards"—should be interchangeable with other systems. "Standards" are parts shared and known throughout a particular field of science to reliably perform the same function.[153] Because these standard parts "must be used together," innovators share "a strong incentive to create entire libraries of parts, in much the same way that software companies develop multiple programs to cover a range of applications."[154] Thus, proponents of an open source business model believe that implementation of the model will achieve this goal in the quickest way possible.[155]

Furthermore, proponents of an open source business model want it to

143. Maurer, *supra* note 11, at 806.

144. Henkel & Maurer, *supra* note 10, at 1.

145. *Id.*

146. *Id.*; *see also* Torrence, *supra* note 4, at 39 (like computer engineers, synthetic biologists also use multiple parts when working on a new product).

147. Henkel & Maurer, *supra* note 10, at 1.

148. *Id.*

149. Maurer, *supra* note 11, at 806.

150. *Id.*

151. *Id.*

152. Henkel & Maurer, *supra* note 10, at 1; *see also* Ledford, *supra* note 40, at 16 (synthetic biology's success "hinges on the creation of standardized parts that can be combined in predictable ways").

153. *See* Torrance & Kahl, *supra* note 5, at 206 (noting that the types of standards that would be necessary include physical composition standards, functional composition standards, units of measurement standards, and data exchange standards).

154. Henkel & Maurer, *supra* note 10, at 2.

155. *See generally* Henkel & Maurer, *supra* note 10, at 2 (noting that creating libraries of standards is key to an open source business strategy).

displace the current patent system because of the costs imposed by patents.[156] Proponents of an open source business models believe that the current patent system inhibits innovation and that the open source business model can drive innovation.[157] One concern with the patent system is the broad reach of foundational patents and their ability to impede downstream research.[158] Another issue is the winner-take-all mentality of the patent system.[159] The first innovator, or at least the first to the patent, is given a monopoly on his innovation.[160] In order to compete with companies that follow the current patent based business model of winner-take-all, synthetic biology companies could look towards an open source business model—like what Linux did to compete with Microsoft.[161]

C. Where is Open Source Currently Used in Science?

Open source business models are starting to become relevant in the field of synthetic biology and biotechnology. For example, the International Genetically Engineered Machine (iGEM) Foundation has established the registry of Standard Biological Parts.[162] iGEM allows others to use these parts but requires users to "contribute the parts they make to the Registry in the spirit of the 'Get & Give' philosophy."[163] Benefits of the registry include an easily accessible catalog of parts and devices, documentation and characterization of all parts that are user-tested, a registry repository for samples, the BioBrick Standard,[164] and an open community where professionals share information and experiences.[165]

Another proponent of an open source synthetic biology community is the BioBricks Foundation. BioBrick's mission statement is to "ensure that the engineering of biology is conducted in an open and ethical manner to benefit all people and the planet."[166] The purpose of the organization is to "launch an open-source community" for synthetic biology.[167] BioBrick has created a

156. Kumar & Rai, *supra* note 28, at 1747.

157. *Id.;* Hirsch & Hsu, *supra* note 10 (Elon Musk of Telsa Mortors Inc., for example, believes that "patents are bad because they stifle innovation and creativity and encourage litigation").

158. *See supra* Part III.B.

159. Henkel & Maurer, *supra* note 10, at 1.

160. *Id.* at 2.

161. *Id.*

162. *Registry of Standard Biological Parts*, IGEM, http://parts.igem.org/Main_Page (last visited Mar. 24, 2015).

163. *Synthetic Biology based on Standard Parts*, IGEM, http://igem.org/About (last visited Mar. 24, 2015) (iGEM was spun off from MIT).

164. The BioBrick Standard "ensures compatibility between parts, allowing them to be assembled together" with other parts into complex systems. *Help: Philosophy*, IGEM, http://parts.igem.org/Help:Philosophy (last visited Mar. 24, 2015).

165. *Id.*

166. *About*, BIOBRICKS FOUND., http://biobricks.org/about-foundation/ (last visited Mar. 24, 2015).

167. Fitzpatrick, *supra* note 14, at 1371–72.

"BioBrick Public Agreement (BPA)" that allows "individuals, companies, and institutions" to use parts and to "make their standardized biological parts free for others to use."[168] The BPA contract requires the contributors to make an "irrevocable promise not to assert any existing or future intellectual property rights" over any part used by other parties to the contract—the users.[169] The users promise to "provide attribution to the Contributor, where requested, and to respect biological safety practices and applicable laws."[170]

Similarly, the International HapMap Project is another open source synthetic biology community that maintains the "HapMap" catalog.[171] The "HapMap" is a catalog of "common genetic variants that occur in human beings."[172] The purpose of the project is to "provide information that other researchers can use to link genetic variants to the risk for specific illnesses, which will lead to new methods of preventing, diagnosing, and treating disease."[173]

Rather than sharing actual parts, the International HapMap Project shares "the genetic sequences of different individuals to identify chromosomal regions where genetic variants are shared" to help other biomedical researchers.[174]

Another company that has created a parts library is Illumina, Inc.[175] Illumina's main source of business, however, is genomic sequencing and other genotyping services.[176] While Illumina utilizes patents for most of their products, they also have a data library freely available on their website.[177] Illumina is unique as it asserts copyright protections on this data library.[178]

Likewise, the medical field has utilized open source strategies as well.[179] Most initiatives in the medical field concern open source software rather than

168. *The BioBrick™ Public Agreement (BPA)*, BIOBRICK FOUND., https://biobricks.org/bpa/ (last visited Mar. 24, 2015).

169. *Frequently Asked Questions*, *supra* note 64.

170. *Id.*

171. *What is the HapMap?*, THE INTERNATIONAL HAPMAP PROJECT, http://hapmap.ncbi.nlm.nih.gov/whatishapmap.html.en (last visited Mar. 24, 2015).

172. *Id.*

173. *Id.*

174. *About the HapMap*, THE INTERNATIONAL HAPMAP PROJECT, http://hapmap.ncbi.nlm.nih.gov/thehapmap.html.en (last visited Sept. 9, 2014).

175. *Data Library*, ILLUMINA, http://science.illumina.com/science/data_library.ilmn (last visited Sept. 9, 2014).

176. *Illumina Fact Sheet*, ILLUMINA, http://www.illumina.com/company/about-us/fact-sheet.html (last visited Jan. 21, 2014).

177. *Id.*

178. *See infra* Part V. A. This Comment will discuss Illumina's unique open parts strategy.

179. Shawn N. Murphy et al., *Architecture of the Open-source Clinical Research Chart from Informatics for integrating Biology and the Bedside*, AMIA ANNUAL SYMPOSIUM PROCEEDINGS 548, 548–52 (2007), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2655844/ (i2b2 hive is an open source software platform for managing medical records and associated genomic data for research. "One of the goals of i2b2 is to provide clinical investigators broadly with the software tools necessary to collect and manage project-related clinical research data in the genomics age as a cohesive entity, a software suite to construct and manage the modern clinical research chart.").

actual medical research.[180] Open source initiatives in the medical field continue as well as open source initiatives in the biotechnology fields.

Although many companies have begun open source initiatives or something similar, efforts for an open source community are only in the initial stages.[181] Researchers will need to collaborate with each other in order to create standard parts and a standard parts library.[182] Consequently, a researcher can then mix and match parts from various libraries for a final product at any part of the world. iGEM, for example, adheres to the BioBrick Standard, which seems to be the dominant standard in the industry.[183] Types of standards that would be necessary include physical composition standards, functional composition standards, units of measurement standards, and data exchange standards.[184]

D. Benefits of Open Source

There are many benefits that open source business models would have for synthetic biology. First, the model allows companies the opportunity to share both their research and their development costs.[185] Consequently, other companies with access to that research would save on the costs for conducting similar research.[186] Likewise, developmental costs for individual parts would decrease if parts are shared and reused.[187] Companies would be able to buy more parts rather than develop parts in house.

180. Hirsch & Hsu, *supra* note 10. Tesla, for example, recently decided to open up its patents to "allow other manufacturers to use its patents in 'good faith' — essentially barring those users from filing patent-infringement lawsuits against the electric car company or trying to produce knockoffs of Tesla's cars."

181. Maurer, *supra* note 11, at 806; *see also* A. L. Rector et al., *OpenGALEN: Open Source Medical Terminology and Tools*, AMIA ANNUAL SYMPOSIUM PROCEEDINGS 982, 982 (2003), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1480228/. An open source project is the OpenGALEN Foundation for a large ontology of the medical domain concerning human anatomy. "Currently available open source resources include a sophisticated ontology development environment and a large open source description logic-based ontology for the medical domain."

182. A "standard" is basically a universally understood norm. Thus, if the industry followed a standard, everyone would be able to understand it. Torrance & Kahl, *supra* note 5, at 206–10. For example, the standard of good faith—it is universally understood to act in good faith. *Id.* Similarly, it is important for parts to adhere to a Standard so that it may be used seamlessly and universally. *Id.*

183. The BioBrick Standard "ensures compatibility between parts, allowing them to be assembled together" with other parts into complex systems. *See Help: Philosophy*, *supra* note 166.

184. *See* Torrance & Kahl, *supra* note 5, at 206; s*ee also* Henkel & Maurer, *supra* note 10, at 2 ("[t]he fact that different parts must be used together also gives actors a strong incentive to create entire libraries of parts, in much the same way that software companies develop multiple programs to cover a range of applications.").

185. Maurer, *supra* note 11, at 807.

186. *Id.*

187. Henkel & Maurer, *supra* note 10, at 1; Pearce, *supra* note 76, at 519 (Costs would be further cut because most license fees would no longer be necessary.).

Second, these parts[188] would also be better than those developed in-house. Presumably, all those who use the parts would be able to patch up any issues in the genetic code of the part used to ensure that the part can be used again.[189] Accordingly, the company that shared the part would expect others to find and improve the part—much like how open source software works.[190] As a result, shared parts will be more reliable.

Third, with an open source business model, individual parts will become relatively inexpensive.[191] Parts purchased repeatedly will become less expensive.[192] Once a company knows that a particular part is useful and the demand for said part is high, it will naturally work to increase the supply of the product. As a result, the company will figure out ways to mass-produce the part, saving money on production costs, which would in turn decrease purchase pricing.

Fourth, companies could produce new products, based on shared parts, at a faster rate.[193] If multiple parts are freely available, companies can produce larger and more useful products quicker. Furthermore, as more parts are utilized and patched, there will be fewer issues making sure different parts are compatible in the same system—which is a common issue researchers deal with when creating biological systems.[194] Access to large libraries of standard parts will allow researchers to think of final products rather than spending time creating the parts necessary for the final product.[195]

Fifth, costs would decrease in producing a final product.[196] Access to cheap and interchangeable parts will not only increase production time, it will also decrease costs for the final products. Likewise, transaction costs on pa-

188. S*ee* Torrance & Kahl, *supra* note 5, at 203 ("[i]n theory, negative effects caused by patent rights covering commonly used components or methods in synthetic biology could be exacerbated if those patented components or methods were to be adopted as standards.").

189. Henkel & Maurer, *supra* note 10, at 1.

190. Sigmond, *supra* note 123, at 90; John C. Newman & Robin Feldman, *Copyright and Open Access at the Bedside*, 365 N. ENG. J. MED. 2447, 2449 (2011), http://www.nejm.org/doi/full/10.1056/nejmp1110652. "Google, Apple, Facebook, and Twitter all use open-source software at the heart of their products, because there is a clear economic benefit to using well-tested, well-validated, continually improved software in the core of complex products. Similarly, there is a clear clinical benefit to using well-tested, well-validated, continually improved clinical tools in complex patient care."

191. Henkel & Maurer, *supra* note 10, at 1.

192. *Id.*

193. Maurer, *supra* note 11, at 807.

194. Henkel & Maurer, *supra* note 10, at 1.

195. T.Y. Leong et al., *Free and Open Source Enabling Technologies for Patient-Centric, Guideline-Based Clinical Decision Support: a Survey*, EUROPE PMC FUNDERS AUTHOR MANUSCRIPTS 1 (April 23, 2010), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2858818/pdf/ukmss-29401.pdf. "There are active and growing trends of deploying [Free Open Source] enabling technologies for integrating clinical guidelines, protocols, and pathways into the main care processes. The continuing development and maturation of such technologies are likely to make increasingly significant contributions to patient-centric, guideline-based clinical decision support."

196. *Id.*

tents would not be an issue. Thus, the developer would save on those transaction costs as well.

Sixth, "gaining reputation through publication is a particularly strong" incentive for biologists.[197] Likewise, biologists may have a number of other individualized motives including learning new skills, goodwill, and impressing potential employers.[198] Although these motives may be limited, open source business models would not exist without them.[199]

E. Costs and Risks with Open Source

Although benefits of an open source business model are numerous, there are also many risks and costs associated such business strategies. Some problems include "incentivizing entities to participate, maintaining openness once it is established, and creating useable biomedical products."[200]

First, incentives for implementing an open source business model are limited.[201] Some examples include individual motives of gaining reputation and impressing potential employers.[202] However, these incentives are not monetary incentives. By choosing an open source business model, an innovator is essentially giving away his hard work to the world for free rather than attempting to commercialize the finding with a patent.[203] Accordingly, incentives are limited.

Second, companies that can afford patents tend to file for patents for many reasons. To begin, patents offer strong protection for innovations created, whereas intellectual property out in the open is not protected.[204] Furthermore, patents help increase a company's economic value—which in turn attracts investors and business partners.[205] Patented genetic sequences "constitute one of the most valuable assets owned by biotechnology companies.[206] Patents are exchangeable and valuable commodities that foster productivity.[207] Thus, companies that can afford patents have very little incentive to implement an open parts strategy.

Third, companies that do implement an open source business model have limited protections for their work once they publish their findings.[208]

197. Maurer et al., *supra* note 117, at 171–72.
198. *Id.*
199. Maurer, *supra* note 11, at 807.
200. Fitzpatrick, *supra* note 14, at 1364.
201. Maurer et al., *supra* note 117, at 171–72.
202. Maurer, *supra* note 11, at 807.
203. *See* 35 U.S.C. § 102 (2014). Public information cannot be patented (with limited exceptions).
204. *Id.*
205. Torrance, *supra* note 4, at 15–16.
206. *Id.*
207. *Id.* at 16.
208. Maurer et al., *supra* note 117, at 172.

Innovators fear that members of an open source project might divert "donated information into unauthorized commercial research."[209] Accordingly, donors are hesitant to fund such projects that do not have guaranteed results.[210] Patents, however, provide a "way of sorting out the competing claims of participants" and allow the original innovator complete rights to his findings.[211]

Fourth, companies that do adopt an open source strategy often have trouble incentivizing other entities to participate in the project.[212] Just as donors are hesitant to donate funds to a project, individual companies are hesitant to participate.[213] Entities may similarly fear that their contributions will be improperly commercialized without receiving just compensation.[214] There is no guarantee that once information is shared that others will share their findings in return.[215]

Fifth, innovation may be slower in an open parts business model. If everything is open source, then there is essentially no incentive to be the first innovate. While patents reward the first to innovate, open source business models have no comparable incentives.[216] Thus, creating useable parts, biomedical products may take longer than if there were proper incentives to work faster.

Sixth, synthetic biology intellectual property has no forms of legal protection other than patents.[217] Accordingly, entities are reluctant to share their work. They fear that their hard work will be stolen, and they will not be adequately rewarded for their hard work. Thus, in order to donate information, the donor essentially forfeits any intellectual property rights to the information.[218] Specifically, unlike software codes, coded genetic sequences do not have any copyright protections.[219]

F. Cost Benefit Analysis for Implementing an Open Source Business Model

When debating whether or not join an open source movement, synthetic biologists must weigh and balance the different risks and benefits associated with open source business models. As previously mentioned, companies that can afford patents are likely to obtain patents. However, as patents are expensive, open source strategies are more appealing to those

209. *Id.*
210. *Id.*
211. Torrance, *supra* note 4, at 16.
212. Fitzpatrick, *supra* note 14, at 1364.
213. Maurer et al., *supra* note 117, at 172.
214. *Id.*
215. *See* Fitzpatrick, *supra* note 14, at 1374.
216. Henkel & Maurer, *supra* note 10, at 2.
217. *See* Maurer, *supra* note 11, at 808.
218. *See* Fitzpatrick, *supra* note 14, at 1376.
219. Maurer, *supra* note 11, at 808.

who cannot afford patents. Consequently, if a company decides to implement an open source business model, they cannot seek the protection of a patent. Companies that do implement an open source business model have limited protections for their work once they publish their findings.[220] Open source projects in the software industry utilize copyright protections, which are currently unavailable to genetic sequences.[221] Thus, synthetic biologists fear that shared information might be unfairly commercialized.[222]

In addition to the lack of other intellectual property protections for genetic sequences, incentives for utilizing open source strategies are limited. Whether or not an innovator decides to utilize an open source strategy heavily depends on that innovator's own personal incentives.[223] For example, most common incentives include increasing one's reputation, a desire for goodwill, impressing potential employers, or learning and acquiring new skills.[224] If an individual does not have a personal incentive to share information, other incentives to join an open source project are limited.[225] This lack of other incentives directly links to the fact that synthetic biology lacks other forms intellectual property protections.[226]

Despite the lack of protections and incentives, open source business models are appealing to synthetic biologists. In theory, an open source strategy allows innovators to share both their research and their development costs.[227] Were it not for the risks associated with open source business models, innovators would be more willing to join open source initiatives. However, due to the lack of intellectual property protections for synthetic biology, open source projects have failed to gain widespread traction worldwide.

V. POSSIBLE SOLUTIONS TO THE ISSUES WITH OPEN SOURCE

Arguably, the greatest deterrent to an open source strategy is the lack of intellectual property protections for synthetic biology innovations. Other than patents, no other form of IP protection is available for genetic codes. For example, trademark protections are extremely limited in scope. Although trade secrets may be utilized to protect genetic information, this type of protection clashes with the concept of the open source strategy. If a company did try to utilize trade secrecy while sharing the physical parts without the sequences, other scientists could simply reverse-engineer the part to discover the sequence.[228] Furthermore, if a third party independently discovered the

220. *See* Maurer et al., *supra* note 117, at 172.
221. Torrance & Kahl, *supra* note 5, at 227.
222. *See* Maurer et al., *supra* note 117, at 171.
223. *Id.* 171–72.
224. Maurer, *supra* note 11, at 807.
225. Fitzpatrick, *supra* note 14, at 1364.
226. Contributors fear that contributions will be improperly commercialized without receiving just compensation. *See* Maurer et al., *supra* note 117, at 172
227. Maurer, *supra* note 11, at 807.
228. *Id.* at 808.

genetic sequence or code supposedly protected as a trade secret, that property right disappears.[229] Another "problem with trade secrets is that—unlike patents or copyright—a single unauthorized disclosure can destroy protection."[230] Thus, trade secret protection is a risky and unreliable source of protection for synthetic biologists.

The only protection that would make sense for genetic codes would be copyright protections. However, DNA sequences and genetic data is not copyright eligible.[231] The only existing type of protection for genetic data would be contractual—where parties would be contractually obligated to follow the rules of the open source project.[232] Part A first analyzes the benefits of copyright protections for genetic sequences if extended to the field of synthetic biology. Parts B and C discuss licenses and contractual protections utilized in open source business models. Finally, Part D discusses how the government can help spur open source movements in the field of synthetic biology.

A. Copyrights

If copyright law extended to the field of synthetic biology, it would be "relatively straightforward to implement open-source synthetic biology in an analogous fashion to open-source software."[233] Copyright affords legal protection against unauthorized copying for "original works of authorship fixed in any tangible medium of expression, now known or later developed."[234] Thus, if copyright law was to extend to synthetic biology, the actual codes—which are of value—could be protected.

Unlike patent law, copyright law includes a provision that explicitly allows several significant uses of copyrighted works without resulting in liability for infringement" in § 107 of the Copyright act known as the "Fair Use" statute.[235] This statute allows copyrighted works to be used for purposes such as "criticism, comment, news reporting, teaching. . ., scholarship, or research."[236] This fair use defense creates a substantial "safe harbor within which socially valuable activities, such as academic research, may survive, and perhaps, even thrive."[237]

Furthermore, extending copyright protection to genetic sequences would allow for a much cheaper and quicker route to protection compared to

229. *Id.* at 809.
230. *Id.*
231. Torrance & Kahl, *supra* note 5, at 227.
232. Kumar & Rai, *supra* note 28, at 1765.
233. Fitzpatrick, *supra* note 14, at 1378.
234. 17 U.S.C. § 102 (2012).
235. Torrance, *supra* note 4, at 38.
236. 17 U.S.C. § 107 (2006).
237. Torrance, *supra* note 4, at 39.

patent protection.[238] Likewise, the protection would last longer as copyright protections generally last for at least 70 years versus the 20 years of a patent.[239] Furthermore, unlike patents which provide for a monopoly on the sequence, fair use doctrines would allow others—especially those in academia—to use the information more freely.[240] This in and of itself would create an open source network for synthetic biologists.

Although current copyright law does not extend to synthetic biology, Illumina, Inc. asserts copyright protection for some if its genetic sequences.[241] In addition to the legal terms on its website, Illumina asserts copyright protection for oligonucleotide primers compatible with its DNA sequencing machines as evidenced by a letter it had sent to customers.[242] It is unclear whether Illumina asserts this legal protection as a scare tactic or if they know something that is unknown to everyone else.

Given the similarities between source code and genetic code, many scientists argue that copyright law should protect genetic sequences.[243] However, synthetic biology is not discussed as "copyrightable subject matter in the US copyright statute."[244] Furthermore, "there is currently no indication that the U.S. Copyright Office or Congress would approve the use of Copyright Law to protect DNA sequences"[245] Accordingly, synthetic biologists will have to wait for the either the Courts or congress to address the applicability of copyright law to synthetic biology.

B. Licenses

Because protection under copyright laws for genetic sequences is still unclear, a viable alternative—for protecting information for open source business models—is protection through licensing. Essentially, licenses would require entities—who wish to participate and use information shared in open source libraries—to sign a contract where they promise not to misuse the information shared. Licenses of this nature are *copyleft licenses*.[246]

Copyleft licenses allow a user to utilize the code of a product but protect the new products or uses found for the code.[247] Copyleft Licenses require any user who uses the source code, modified or not, to "re-license" the product under "identical terms that allow any recipient to change the code" as

238. Torrance & Kahl, *supra* note 5, at 227.
239. 17 U.S.C. § 302 (2012).
240. Torrance & Kahl, *supra* note 5, at 227.
241. *Id.* at n.153.
242. *Id.*
243. *Id.* at 203.
244. Rai & Boyle, *supra* note 2, at 391.
245. Fitzpatrick, *supra* note 14, at 1384.
246. Heather Meeker, *Open Source and the Secrets of Commando Due Diligence*, 43 TEX. J. BUS. L. 561, 562 (2009).
247. *Id.*

well.[248] In this manner, entities do not need to worry about who misuses their products.

Copyleft licenses are very common in open source software projects.[249] Not only do these licenses allow information to be freely available, but they "also require those who distribute improvements to the source code to make the improvements available on the same terms."[250] Accordingly, these contracts would help ensure that the sequences shared are continually improved. In the software industry, these "licenses have produced well-functioning code," and prevented software from threats posed by copyright and patent—which would limit the free use of the software.[251]

Although copyleft licenses have worked for the software industry, there is no guarantee that the same success will transfer over to genetic sequences.[252] For instance, copyleft licenses for software often utilize copyright law as another layer of protection to prevent individuals from copying and misusing information. As mentioned previously, this layer of protection is not necessarily available to synthetic biology. Furthermore, unlike the software industry, synthetic biology requires extensive and expensive clinical trials and testing to ensure that the codes are fully functional.[253] Patents have been traditionally used to protect R&D costs by allowing the holder to exclusively commercialize the product as a monopoly for a short period of time.[254] If licenses displace patents, there will be no legal monopoly for the developer to utilize.

One particular copyleft license that open source movements in the software industry have utilized is the General Public License (GPL).[255] The GPL could easily be "adapted to cover DNA and would have the same open-source effect."[256] A modified GPL would allow genetic sequences or novel combinations of sequences to be protected but available to the public.[257]

C. Contracts

If a company does not have a license to sublicense a patent or other work, general contracts might be an alternative to promote open source busi-

248. *Id.*; Newman & Feldman, *supra* note 190. "Copyleft is intellectual jujitsu that uses copyright protection to guarantee the right of anyone to use, modify, copy, and distribute a work, as long as it and any derivatives remain under the same license. The author retains the right to offer the work under a different license simultaneously — for example, giving a company specific license to commercialize the work without copyleft protections."

249. Rai & Boyle, *supra* note 2, at 391.

250. *Id.*

251. *Id.* at 392.

252. *See* Maurer et al., *supra* note 117, at 172.

253. Rai & Boyle, *supra* note 2, at 392.

254. *Id.*

255. Fitzpatrick, *supra* note 14, at 1378.

256. *Id.*

257. *Id.*

ness.[258] Through a contract, parties to an open source project can predetermine all parameters and aspects to the agreement to share and use information.[259] This will also give both parties flexibility and will clearly define the obligations of both parties.[260]

However, contractual protection is not the strongest form of protection nor is it the best route for open source projects. First, the contract would limit the scope of use of the sequences involved in the contract.[261] Second, a contract would only be binding on the parties involved in the actual contract.[262] Thus, intermediaries in any testing processes would not be obligated to follow the actual contract—unless they signed a second contract, which would create an unworkable web of contracts. Third, the larger the open source project, the harder it will be to enforce the contract to each individual entity.[263] Enforcing a contract may even result in excessive lawsuits that can be both time consuming and expensive. Therefore, even though contracts can be extremely flexible, it may not be the best way to protect information in an open source business model.

VI. HOW THE GOVERNMENT CAN ASSIST IN AN OPEN SOURCE APPROACH

The lack of other forms of intellectual property protection for genetic sequences and data is one of the greatest deterrents to an open source movement in the field of synthetic biology. However, this deterrent would not be an issue if Congress or the courts were to extend copyright law to protect synthetic genetic codes. As discussed previously and by many other scholars, an open source movement in the field of synthetic biology would greatly benefit from additional intellectual property protection. If Congress or the courts were to allow genetic data to be copyrightable, then more users would be willing to share their findings with others knowing that the work is protected.[264] Thus, innovators who share information will not have live with the fear that others will unfairly commercialize their work.[265]

There is a second way by which the government can help foster open source strategies in the field of synthetic biology—by providing incentives to share findings with other researchers in the field. The government already contributes significant amounts of funding for scientific research.[266] While providing funding for research projects, if the government were to add addi-

258. Kumar & Rai, *supra* note 28, at 1765.
259. *Id.*
260. *Id.*
261. *Id.*
262. *Id.*
263. *Id.* at 1766.
264. *See supra* Part V.A.
265. *Id.*
266. For example both NIH and DOE provide funding to private scientists. *Research and Development*, LYNNTECH INC. (2012), http://lynntech.com/research_development/.

tional funding incentives to share basic parts with the rest of the community, synthetic biology would see an immediate open parts community and innovation would occur more rapidly.

The government is already funding large projects. For example, the Department of Energy's $350 million "biofuels initiative has no open-parts requirement" but can easily add an incentive to share information.[267] However, not all of those funds are going to the same researcher. While the government is already spending so much money funding projects for various entities, if those entities were to share their findings with others in the field, the government may be able to save money by funding less projects. The government already promotes open source against software monopolies, such as Microsoft, and should extend this practice to the field of synthetic biology.[268] Practitioners would be able to save time and resources by taking advantage of past findings by other scientists in the field. Accordingly, adding incentives to opt for an open source business strategy will both foster innovation and save the government money for funding projects.

As discussed previously, foundational patents hinder innovation.[269] The USPTO must enforce stricter patent guidelines to help limit the scope of patents and prevent foundational patents.[270] Stricter guidelines would ensure that basic parts are not patented. As previously mentioned, the USPTO does not have strict guidelines for patents related to synthetic biology.[271] Defining these guidelines and thus limiting scopes of patents will allow an open source movement to take place. Avoiding patent thickets will help innovators create new products.

Furthermore, the USPTO may consider limiting the term of the patent. If patents are only valid for 10 or 15 years rather than 20, that extra time from which the patent is no longer valid will allow users to create new products faster. In other words, if a basic part is covered for 5 or 10 less years, that part can be used to create new products at a faster rate. However, most patent prosecutors and companies would not prefer to have patent terms limited. Patents are expensive—thus patent holders want to keep their monopoly for as long as possible.

To continue, like the USPTO, either Congress or the Courts should help limit the scope of patents in the field of synthetic biology. Like in *Alice Corp.*, the courts should restrict patents on genetic data and products to limit the patentability of abstract ideas in the field of synthetic biology.[272] This will help synthetic biologists in two ways. First, this will help limit foundational

267. Maurer, *supra* note 11, at 809.

268. *Id.*

269. *See supra* notes 62–72 and accompanying text.

270. Pearce, *supra* note 76, at 521 ("[s]topping patents on basic nanotechnology will create much more innovation than there is now.")

271. Kumar & Rai, *supra* note 28, at 1751.

272. *See supra* notes 110–12 and accompanying text.

patents.[273] Second, clear guidelines on what is or is not patentable will help innovators determine when to seek patents.[274] The past few years have seen "tremendous flux" in how courts interpret nonobviousness and patent-eligibility concerning synthetic biology.[275]

Considering the alternatives to patent protections discussed above, the most viable source of protection is copyright protection. As of now, the Courts are silent as to whether or not genetic sequences can be protected by copyrights.[276] If the Courts or Congress were to dictate that copyright protections could extend to genetic data, open source movements would quickly prosper.[277] Just like software is protected by copyright law and has enjoyed success through open source business strategies, genetic data could similarly benefit from copyright protection.

VII. CONCLUSION

Open source is strongly favored by researchers and innovators, but practitioners are hesitant to make any moves. Proponents of open source business models believe that the flaws in the current patent system hinder advancements in the field of synthetic biology.[278] Some of the issues associated with the patent system include patent thickets and foundational patents. Likewise, uncertainty of what is patent eligible also contributes to the stifling of innovation.[279] Open source business models have many benefits but also have many risks.[280] For instance, benefits of open source strategies include—but are not limited to—shared costs for research and development, better and cheaper products, and quicker innovations.[281] However, risks include a lack of incentives, predominance of patents, and limited non-patent intellectual property protections for genetic data.[282]

The positives of an open source strategy for synthetic biology are extremely significant. Further innovations will allow for greater advancements in the fields of biotechnology, medicine, biofuels, and even agriculture.[283] Practitioners must join open source movements to maximize the movement's value. The government can even help aid the open source movement by cre-

273. *Contra supra* note 65 and accompanying text.

274. *See supra* notes 66–71 and accompanying text.

275. *See* Torrance & Kahl, *supra* note 5, at 203 ("[i]n practice, the past few years have seen tremendous flux in how courts interpret the patent-eligibility of both methods, such as diagnostic tests, and components, such as isolated DNA molecules, essential to synthetic biology.").

276. *See supra* notes 235–36 and accompanying text.

277. *See supra* notes 224–25 and accompanying text.

278. *See supra* Part III.B.

279. *Id.*

280. *See supra* Parts IV.D., IV.E.

281. *See supra* Part IV.D.

282. *See supra* Part IV.E.

283. *See* Kumar & Rai *supra* note 8, at 1746.

ating incentives for researchers funded by the government.[284] However, there are still many risks associated with such strategies, namely a lack of non-patent intellectual property protection.[285] Until the risks associated with open source strategies are limited, practitioners will continue to be hesitant to join open source projects.[286] Innovators fear that if they share and participate in an open source project, others might take advantage of shared information.[287] Given the lack of intellectual property protections for genomic sequences and data, innovators are unwilling to risk sharing their research and findings with potential competitors.[288] Protection from copyright laws would help alleviate such fears as innovators will have a layer of legal protection when sharing information.[289] The software industry and companies such as Linux have thrived in open source systems because software and source code can be protected by copyrights.[290] Innovators believe that similar protections for genetic sequences would allow synthetic biology to thrive in an open source system.[291]

In conclusion, open source business models would be extremely beneficial to synthetic biologists. Even though there are open source projects currently underway, the projects are only in initial stages.[292] Innovators are arguably justified in being hesitant to join such movements. However, because the benefits of open source business models are significant, application of open source business models to synthetic biology will be of much debate for some time.

284. *See supra* Part V.

285. *See supra* Part IV.F.

286. H. Schmuhl, O. Heinze, & B. Bergh, *Use of Open Source Software in Health Care Delivery – Results of a Qualitative Field Study*, 13 IMIA YEARBOOK OF MEDICAL INFORMATICS 107, 107 (2013), http://www.apfelkraut.org/download/IMIA_YB_2013_Use_of_Open_Source_Software_in_Health_Care_Delivery.pdf. This holds true in the medical field as well. "In order to capitalize the unique advantages of [Open Source strategies] in a clinical setting, complex requirements need to be addressed. Shortcomings of OSS describe an attractive breeding ground for new commercial offerings and services that need yet to be seen.

287. Maurer et al., *supra* note 118, at 172.

288. *Id.*

289. *See supra* Part V.A.

290. Fitzpatrick, *supra* note 14, at 1378.

291. *Id.*

292. Maurer, *supra* note 11, at 806.