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Charting the Contours of a Copyright Regime Optimized for Engineered Genetic Code

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CHARTING THE CONTOURS OF A COPYRIGHT REGIME OPTIMIZED FOR ENGINEERED GENETIC CODE

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Abstract

There is a growing disconnect between the traditional patent-centric approach to protecting biotechnological innovation and the emerging intellectual property imperatives of "synthetic biology," a promising new manifestation of biotechnology that enables the design and construction of artificial biological pathways, organisms or devices, as well as the redesign of existing natural biological systems. As explained in previous articles, one way to deal with this disconnect would be to expand the scope of copyrightable subject matter to encompass engineered genetic sequences, much in the way that copyright was expanded in the 1970s and 1980s to include computer programs. The present article expands upon that work and explores the possible contours of a copyright regime encompassing engineered genetic code (EGC), explaining how a policy-optimized application of existing copyright doctrine, facilitated perhaps by some relatively conservative amendments to the Copyright Statute, could provide synthetic biologists with a beneficial supplement to patents, while at the same time addressing legitimate concerns that have been raised in response to this proposal. The use of the term "EGC," as opposed to "DNA," is intended to focus the attention where it rightly belongs, i.e., on the information content encoded by a synthetic genetic sequence, and to make clear that I am in no way proposing that naturally occurring DNA sequences should be copyrighted. It also highlights the close analogy between computer code and engineered DNA sequences. The article includes a description of a recent attempt to register an engineered genetic sequence as a copyrighted work with the U.S. Copyright Office (the "Copyright Office" or "Office").

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I. Introduction

Synthetic biology has been defined as "an emerging area of research that can broadly be described as the design and construction of novel artificial biological pathways, organisms or devices, or the redesign of existing

natural biological systems."[1] In essence, it is the next generation of the biotechnology revolution that began with the development of the foundational tools for engineering DNA, commonly referred to as genetic engineering, in the 1970s.[2] While the earliest products of biotechnology involved relatively simple rearrangements of naturally occurring genetic elements, synthetic biology is characterized by much more extreme deviations from nature.[3] Products of synthetic biology include entirely synthetic genes and complex synthetic genetic systems that increasingly represent works of purposeful human design and engineering rather than mere recombinations of DNA sequences derived from nature.[4] There is great hope that advances in synthetic biology will result in sustainable technologies that address many of society's most pressing concerns regarding healthcare, nutrition, and energy.[5]

If this technology is to live up to its potential, there must be adequate incentives in place to fund the research, development, and commercialization of synthetic biology products. As explained in a previous article, however, there is a growing disconnect between the traditional, patent-centric approach to protecting biotechnological invention and the intellectual property imperatives of synthetic biology.[6] That article suggested that one way to deal with this disconnect is to expand copyright to encompass synthetic DNA sequences in the same way that copyright was expanded in the 1970s and 1980s to encompass computer programs.

I have explained in another article that some forms of engineered DNA sequences should be considered copyrightable subject matter, and indeed that such an expansion of the recognized scope of copyright would not require any revision of the Copyright Act.[7] In the present article, I expand upon that work and explore the possible contours of a copyright regime that would encompass synthetic DNA. Significantly, the present article focuses the discussion primarily on copyright for what I will refer to as "engineered

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1. *Synthetic Biology 101: What Is Synthetic Biology?*, SYNTHETIC BIOLOGY PROJECT (citation omitted), http://www.synbioproject.org/topics/synbio101/definition/ (last visited Aug. 8, 2016).

2. Christopher M. Holman, *Developments in Synthetic Biology Are Altering the IP Imperatives of Biotechnology*, 17 VAND. J. ENT. & TECH. L. 385, 388-403 (2015) [hereinafter Holman, *Developments*].

3. *Id*. at 418-41.

4. *Id*.

5. *Id*.

6. *Id*. at 442-54.

7. *See generally* Christopher M. Holman, *Copyright for Engineered DNA: An Idea Whose Time Has Come?*, 113 W. VA. L. REV. 699 (2011) [hereinafter Holman, *Copyright*].

genetic code" ("EGC"), rather than DNA *per se*. In so doing, my intent is to focus the attention where it rightly belongs, i.e., on the information content encoded by a synthetic genetic sequence.

This distinction between copyright for EGC and copyright for DNA is significant and bears emphasis. Historically, any discussion of extending copyright to biotechnology has tended to cast the debate in terms of "copyright on DNA," which, for a host of reasons, is loaded terminology invoking concerns about the possibility of property rights extending to naturally occurring genes and, indeed, the ownership of human beings themselves. In fact, DNA is best conceptualized as a medium for storing and conveying genetic information, analogous to a DVD on which a copyrighted audiovisual work is recorded, or the ink and paper traditionally used to store and convey an author's literary expression. It is not the physical material comprising the book, DVD, or DNA that is copyrighted, or for that matter which provides value, but rather the information embodied in the medium.

EGC represents a form of human-made expression that is closely analogous to engineered computer code, and, as is the case with most copyrighted works, EGC can be embodied in a variety of mediums. DNA is of course one of the most important of these mediums, but there are others, such as RNA, a related class of macromolecules that, while chemically similar to DNA, is nonetheless physically and functionally distinct. There are also a variety of synthetic analogues of RNA and DNA which can be used to embody EGC and to convey its information content.

Furthermore, EGC can be represented in a variety of non-biological media by, for example, writing the sequence down on a piece of paper or recording it on computer-readable media. EGC embodied in such non-biological media is entirely analogous to representations of computer code that are directed toward a human reader rather than a machine, as printed source code might be read from paper. Although EGC constitutes only one aspect of biotechnology, it is an extremely important one and could be leveraged to provide meaningful and appropriately tailored protection for a variety of important biotechnological innovations.[8]

The present article explains how a policy-optimized application of existing copyright doctrine, facilitated perhaps by some relatively conservative amendments to the Copyright Statute, could provide a

8. *See Guide to Biotechnology 2008*, BIOTECHNOLOGY INNOVATION ORG., http://www.bio.org/sites/default/files/files/BiotechGuide2008.pdf (last visited May 12, 2016) ("DNA [is] the cornerstone of biotechnology").

beneficial supplement to patents, while at the same time addressing the concerns of skeptics. Part II describes growing interest in an extension of copyright to EGC, not only among academics, but also intellectual property attorneys and biotechnologists. Part III describes a recent collaborative attempt by myself, a law professor, and a leading synthetic biology company to register an engineered genetic sequence as a copyrighted work with the U.S. Copyright Office. Part IV explains how copyright could provide a useful and socially desirable supplement to patent protection but would not entirely supplant the role of patents in protecting EGC. Part V discusses various attributes of a copyright regime that protects EGC in a manner that advances innovation policy. Part VI, the heart of the article, explores the manner in which existing copyright doctrine could be applied to EGC in a manner best suited to promote public policy, which could involve congressional action.

II. A Growing Interest in Copyright for EGC

Academics have long debated whether DNA might be considered copyrightable, and, if so, whether such an expansion of recognized copyrightable subject matter would constitute good policy.[9] Today, however, there appears to be a growing interest among a more pragmatic constituency of non-academics.[10] The earliest example of this of which I am aware comes from a personal conversation I had with a man who served as Chief IP Counsel at a leading gene-discovery company from 1999 to 2002. He told me that, during that timeframe, the company had considered the human genetic sequences it was discovering to be copyrightable and had formally attempted to register them as copyrighted works with the U.S.

9. *See* Holman, *Copyright*, *supra* note 7, at 711-14. *See generally* Dan L. Burk, *Copyrightability of Recombinant DNA Sequences*, 29 JURIMETRICS J. 469, 531–32 (1989); Jorge A. Goldstein, *Copyrightability of Genetic Works*, 2 BIO/TECHNOLOGY 138 (1984); Irving Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 191 (1982); Andrew W. Torrance, *DNA Copyright*, 46 VAL. L. REV. 1 (2011); Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J. L., SCI. & TECH. 629 (2010) [hereinafter Torrance, *Synthesizing Law*]; Donna Smith, Comment, *Copyright Protection for the Intellectual Property Rights to Recombinant Deoxyribonucleic Acid: A Proposal*, 19 ST. MARY'S L.J. 1083, 1096–1108 (1988).

10. *See, e.g.*, Heidi Ledford, *Bioengineers Look Beyond Patents: Synthetic-biology Company Pushes Open-source Models*, 499 NATURE 16 (2013).

Copyright Office. These attempts at registration were apparently denied, and the company does not appear to have appealed these decisions.[11]

Since the publication of my first DNA copyright article, several companies interested in pursuing copyright in engineered DNA sequences have contacted me. For example, an attorney representing a synthetic-biology company (which was developing synthetic microorganisms for use in a variety of applications, such as living biosensors capable of detecting toxins and pathogenic organisms) learned of my work and wanted to know whether I thought copyright could be used to protect his company's products. He explained that the development of these products was an iterative process, involving continual updating and revisions of the underlying EGC, and that patent protection was a poor fit due to the cost and long lag time between the filing of a patent application and issuance of a patent. Trade secret was not up to the task either, since the engineered microorganisms (which inherently incorporate the EGC) were commercial products, and hence widely distributed to customers, much in the way computer software code is inherently made available to customers, and thus difficult to protect by trade secret law. This company's predicament contrasts with more traditional biotechnology companies, particularly those that use bioengineering to produce drugs and are thus able to maintain physical control over engineered organisms and their genetic code.[12] This attorney believed that copyright could play an important role in protecting the company's proprietary EGC. Unfortunately, I had to inform him that copyright for EGC has yet to be recognized, and as a practical matter probably will not be anytime soon.

Agricultural biotechnology could have the most to gain from an extension of copyright for EGC, at least in the near term. I have spoken with one attorney who used to work at a major agricultural biotechnology company, and he explained that his company considered the possibility for years. In fact, he related to me an interesting anecdote. Years ago, he was making a presentation in India to patent examiners, explaining his company's position that engineered DNA and products such as seeds that incorporate engineered DNA should be patentable. One of the patent examiners spoke up and voiced his opinion that engineered DNA should not be patentable, but instead should be protected by copyright.

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11. See *infra* Part III, which describes a letter from the Copyright Office stating that our appeal of the Office's decision to deny registration of an engineered DNA sequence was "a matter of first impression" for the Office.

12. *See* Holman, *Developments*, *supra* note 2, at 422-28.

Attorneys at some of the leading intellectual property law firms in the United States are also seriously considering the potential applicability of copyright to EGC. I have been contacted by a number of attorneys working at these firms who have read my work and share my views regarding the legal and policy justifications for this extension of the scope of copyrightable subject matter. At least one major law firm is actively soliciting clients, looking for one that would be willing to pursue a copyright enforcement action with respect to engineered DNA. I learned of this through a conversation with an attorney currently working at a major agricultural biotechnology company. This attorney shared with me a PowerPoint presentation a law firm had recently presented at his company, essentially explaining that the time is right for biotechnology companies to assert their copyright in EGC by filing copyright infringement lawsuits against unauthorized users of the company's proprietary EGC. It seems only a matter of time before the question of whether EGC can be copyrighted makes its way before the courts.

In fact, one of the companies is so interested in the potential benefits of copyright for EGC that it agreed to work with me on a test case in which we attempted to register a synthetic, engineered DNA sequence with the U.S. Copyright Office as a copyrighted work.[13] The company is ATUM (formerly DNA2.0), a leading synthetic biology company headquartered in Newark, California.[14] Much of ATUM's business involves designing and synthesizing EGC for its customers.[15] In most cases, the company is not particularly interested in patenting this EGC, in part because it would be prohibitively expensive given the large number of engineered sequences the company is producing, particularly in view of the marginal commercial value of many of the sequences (at least compared to the EGC used in the manufacture of traditional biotechnology products such as drugs and seeds). The long lag time involved in getting a patent is also a substantial deterrent for a fast-moving company like ATUM, as is the current uncertainty regarding the patentability of gene-based inventions in the wake of the Supreme Court's *Myriad* decision, which held that at least some synthetic DNA sequences are patent-ineligible.[16]

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13. *See infra* Part III.

14. *See* ATUM, https://www.atum.bio/ (last visited May 13, 2017).

15. *See id.*

16. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); *see also* Mayo Collaborative Servs., v. Prometheus Labs., Inc., 566 U.S. 66, 72 (2012) (holding diagnostic processes applying natural law patent ineligible).

Moreover, ATUM seeks to foster a vibrant public domain in synthetic biology and would rather not contribute to a proliferation of patents that could unnecessarily limit access to building blocks of future innovation in the field.[17] The desire of a company like ATUM to avoid cluttering the innovation landscape with an unnecessary number of patents reflects not only the ethos of many in the synthetic biology community, but also the very practical desire of a DNA-synthesis company to encourage freedom to operate in this technological space.[18]

Much of ATUM's business involves synthesizing DNA sequences to fulfill customers' orders - essentially contract manufacturing. Some customers specify the DNA sequence to be synthesized, while others contract with ATUM to design and synthesize a novel DNA sequence that provides the functional attributes desired by that customer.[19] In either event, trying to assess freedom to operate with respect to patent infringement can be an awesome task, particularly for a relatively lean company like ATUM that receives a multitude of orders for unique DNA sequences from a diverse array of customers. Although patents are publicly available documents that, in principle, provide notice to potential infringers, as a practical matter it can be very difficult and expensive to assess whether or not the manufacture of a synthetic sequence could result in an allegation of patent infringement, and the difficulty increases with the complexity of the sequence.

There are a large number of issued patents relating to DNA sequences that would have to be considered in any thorough assessment of freedom to operate.[20] Patent claims directed towards genetic sequences can be written in very broad terms, encompassing astronomical numbers of variants sharing some degree of structural and/or functional similarity.[21] Even in cases where a third-party patent has been identified, the boundaries of patent claims can be hard to discern, even for an attorney, rendering it difficult at times to assess the potential for infringement liability. In many cases it is impossible to know whether a patent claim encompasses a

17. *See* Ledford, *supra* note 10, at 17.

18. *Id.*

19. *See* ATUM, *supra* note 14.

20. Christopher M. Holman, *Debunking the Myth That Whole-Genome Sequencing Infringes Thousands of Gene Patents*, 30 NATURE BIOTECHNOLOGY 240 (2012) [hereinafter Holman, *Debunking*].

21. *Id.*; *see also* Christopher M. Holman, *Protein Similarity Score: A Simplified Version of the Blast Score as a Superior Alternative to Percent Identity for Claiming Genuses of Related Protein Sequences*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 55, 68 (2004).

product without determining claim scope in the context of patent litigation. Furthermore, many issued patents include invalid claims, but again, it is often the case that the invalidity is only determinable in the context of litigation or post-grant review by the Patent and Trademark Office ("PTO"), both of which can be prohibitively time-consuming and expensive, particularly in the context of synthetic biology.

Patents relating to genes encoding fluorescent proteins provide an illustrative example. These genes have come to play an extremely important role in biotechnology and are used extensively in a variety of applications involving research and analytics. The first fluorescent proteins to be used in this manner were the green fluorescent proteins ("GFPs"), derived from fluorescent jellyfish.[22] The discovery of GFPs not only led to a well-deserved Nobel Prize, but also resulted in a family of patents, including some that include ambiguously drafted claims that could be interpreted as providing broad coverage over later-discovered fluorescent protein genes, potentially even genes with very different structure and functional characteristics than the originally discovered GFPs.[23] These patents ended up in the hands of a patent enforcement company, and resulted in cease-and-desist letters and lawsuits against a number of companies using fluorescent protein technology.[24]

For a company like ATUM, the breadth of many DNA-based patents, compounded by uncertainties regarding their scope and validity, can pose significant problems. A narrower form of intellectual property protection, such as might be provided under a copyright regime that recognizes EGC, would allow an innovator to garner some protection for a useful innovation—like an engineered fluorescent protein—without unduly impeding the ability of others to independently develop functional analogs, which in some cases might provide different or improved functional characteristics.

In fact, the synthetic biologists at ATUM engineered their own novel engineered DNA sequence encoding a fluorescent protein. This synthetic

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22. Press Release, Royal Swedish Acad. of Scis., The Nobel Prize in Chemistry 2008 (Oct. 8, 2008), http://www.nobelprize.org/nobel_prizes/chemistry/laureates/2008/press.html.

23. *See* Tania Bubela & Robert Cook-Deegan, *Keeping Score, Strengthening Policy and Fighting Bad Actors over Access to Research Tools*, 33 NATURE BIOTECHNOLOGY 143 (2015); Christopher Holman, *Judge Calls Anticancer Inc.'s Attempts to Enforce GFP Patents "Misguided," Warns That Future Enforcement Activity Could Warrant an Award of Attorney Fees*, HOLMAN'S BIOTECH IP BLOG (June 30, 2013), http://holmansbiotechipblog.blogspot.com/2013/06/judge-calls-anticancer-incs-attempts-to.html.

24. *See* Bubela & Cook-Deegan, *supra* note 23.

gene, which the company has dubbed "Prancer," achieves its fluorescence by means of a significantly different structural mechanism than original GFP-based proteins.[25] ATUM does not necessarily require broad patent coverage that would preclude others from designing genes with the functional characteristics of Prancer, but would understandably like to have some legal mechanism to stop competitors from free-riding off its investment in time and money. In the absence of some form of IP protection, piracy is extremely easy with respect to EGC like the Prancer gene, owing to the ready availability of gene synthesis machines and the self-replicability of DNA.[26] A pirate would not even need to access a single copy of the original DNA in order to recreate it - the mere publication of the Prancer sequence on the Internet could be used as a basis to cheaply make the gene, which could then be easily replicated.[27]

ATUM believes that, at least in certain cases, copyright protection for synthetic genes like Prancer could provide a more appropriate form of protection than patents. A number of commentators have argued that, from an innovation policy perspective, copyright is the preferred form of protection for software.[28] For similar reasons, the same might be the case

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25. *Prancer Purple Protein*, ATUM, https://www.atum.bio/eCommerce/catalog/datasheet/41 (last visited May 12, 2017).

26. Christopher M. Holman, Bowman v. Monsanto Co.*: A Bellwether for the Emerging Issue of Patentable Self-Replicating Technologies and Inadvertent Infringement*, 80 MO. L. REV. 665, 672-73 (2015) [hereinafter Holman, *A Bellwether*].

27. *See id.* at 669-72.

28. In a recent Federal Circuit opinion, the court noted:

> [S]everal commentators have recently argued [that software is or should be entitled to protection only under copyright law—not patent law]. *See* Technology Quarterly, *Stalking Trolls*, ECONOMIST, Mar. 8, 2014, http://www.economist.com/news/technology-quarterly/21598 321–intellectual–property–after–being–blamed-stymying-innovation-america-vague ("[M]any innovators have argued that the electronics and software industries would flourish if companies trying to bring new technology (software innovations included) to market did not have to worry about being sued for infringing thousands of absurd patents at every turn. A perfectly adequate means of protecting and rewarding software developers for their ingenuity has existed for over 300 years. It is called copyright."); Timothy B. Lee, *Will the Supreme Court save us from software patents?*, WASH. POST, Feb. 26, 2014, 1:13 PM, http://www.washingtonpost.com/blogs/the-switch/wp/2014/02/26/will-the-supreme-court-save-us-from-software-patents/ ("If you write a book or a song, you can get copyright protection for it. If you invent a new pill or a better mousetrap, you can get a patent on it. But for the last two decades, software has had the distinction of being potentially eligible for both copyright and patent protection. Critics say that's a mistake. They argue that the complex and

with respect to some EGC, particularly with advances in synthetic biology blurring the line between software engineering and genetic engineering.[29]

III. Our Attempt to Register EGC as a Copyrighted Work

In the spirit of experimentation and "pushing the envelope," Professor Andrew Torrance (University of Kansas School of Law) and I teamed up with ATUM in a project wherein we sought copyright registration for the Prancer DNA sequence with the U.S. Copyright Office.[30] We did this with the intent of advancing the public conversation regarding the potential applicability of copyright to EGC. Although we fully expected the Copyright Office to deny registration, we thought that by appealing such a decision it would be possible to get the Copyright Office to explain the basis for its position that, while computer code is copyrightable, functionally analogous EGC is not. A denial of registration could potentially be appealed in the federal courts, if we chose to take the matter that far.

There is some precedent for using copyright registration to expand the recognized scope of copyrightable subject matter. For example, in the early 1960s the Copyright Office expressed "profound doubts" as to whether computer programs qualified as copyrightable subject matter.[31] A student at Columbia University Law School challenged the Copyright Office position by filing for registration of a computer program the student had created.[32] In response to this and other requests for registration of computer programs, in 1964 the Copyright Office began to permit registration of computer programs under a "'rule of doubt' . . . leaving the ultimate question of copyrightability to the courts."[33]

> expensive patent system is a terrible fit for the fast-moving software industry. And they argue that patent protection is unnecessary because software innovators already have copyright protection available.").

Oracle Am., Inc. v. Google Inc., 750 F.3d 1339, 1380 (Fed. Cir. 2014) (second alteration in original).

29. Holman, *Developments*, *supra* note 2, at 421-22.

30. Christopher M. Holman, Claes Gustafsson & Andrew W. Torrance, *Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression*, 35 BIOTECHNOLOGY L. REP. 103, 103-05 (2016).

31. Pamela Samuelson, *CONTU Revisited: The Case Against Copyright Protection for Computer Programs in Machine-Readable Form*, 1984 DUKE L.J. 663, 692–93.

32. *See* William F. Patry, *Copyright and Computer Programs: A Failed Experiment and a Solution to a Dilemma*, 46 N.Y. L. SCH. L. REV. 201, 201-03 (2003).

33. Samuelson, *supra* note 31, at 692, 693.

Judicial appeal of a Copyright Office registration denial is one means by which the question of copyrightability of EGC could be brought before the courts.[34] This was the route through which the copyrightability of videogame displays, for example, was established. In that case, the Copyright Office had repeatedly rejected Sega's attempts to register the videogame BREAKOUT as an audiovisual work, based on the Office's conclusion that "the display screens both individually and as a whole simply lack[ ] sufficient creativity to make them registerable as audiovisual works."[35] On appeal, the D.C. Circuit found that the Copyright Office had erred by applying an overly stringent standard of creativity, pointing out that "[t]he vast majority of works make the [copyright] grade quite easily."[36]

Not surprisingly, our request to register Prancer was initially rejected by the Office, with no meaningful explanation. In pursuit of a more in-depth explanation, we submitted a request for reconsideration (the "Appeal") on November 26, 2012.[37] In our request, we argued that human-designed DNA sequences such as Prancer fall comfortably within the category of "literary work" explicitly specified as copyrightable in the statute for substantially the same reasons that computer programs are currently treated as literary works eligible for copyright protection.[38] Our Appeal explained that, as an original work of authorship "fixed in [a] tangible medium of expression," the Prancer DNA sequence appears to satisfy the various statutory requirements of copyright, particularly given the Copyright Statute's expansive and flexible definition of copyrightable subject matter.[39] We also emphasized the potential policy benefits that would accompany a recognition of copyright protection for engineered genetic code.

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34. *See* Proline Concrete Tools, Inc. v. Dennis, No. 07CV2310-LAB AJB, 2012 WL 2886953, at *1 (S.D. Cal. July 13, 2012), *vacated on reconsideration*, 2013 WL 12116134 (S.D. Cal. Mar. 28, 2013). The other would be a copyright infringement litigation, which could be filed even in the absence of registration, so long as the copyright owner at least attempted registration. *See* 17 U.S.C. § 411(a) (2012).

35. Atari Games Corp. v. Oman, 979 F.2d 242, 243 (D.C. Cir. 1992) (alteration in original) (citation omitted).

36. *Id.* at 247 (citing Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 345 (1991)).

37. DNA 2.0, Inc., *Supplementary Document 1: Request for Reconsideration of Denial of Copyright Registration of Prancer DNA Sequence*, 35 BIOTECHNOLOGY L. REP. 113 (2016).

38. *Id.* at 114-15.

39. *Id.*

In February 2014, after more than fourteen months had elapsed, we received a letter from the Copyright Office responding to our request for reconsideration (the "Denial").[40] The Denial was signed by Robert Kasunic, Associate Register of Copyrights and Director of Copyright Policy and Practices, and began by apologizing for the delay in responding to our request, explaining that "this request was an issue of first impression for the U.S. Copyright Office and as such, was given significant consideration prior to rendering a decision."[41] The letter goes on to state that "after carefully reconsidering the registration materials and the arguments contained in your request reconsideration, the Office affirms the refusal registration."[42]

The Denial sets forth both policy and legal rationales purporting to support the Office's decision to refuse registration. We could have petitioned the Copyright Office a second time to reconsider its refusal to register and then proceeded to challenge the decision in the courts, as Sega did with respect to videogame displays. After reading the Denial, however, we concluded that further appeal to the Copyright Office would almost certainly be futile, and an appeal to the courts would require the expenditure of more time and money than ATUM was prepared to spend at that time.

We wrote a short article describing in greater detail the result of our attempt to register the Prancer DNA sequence, including a detailed response that we believe refutes the Office's stated rationale for denying registration.[43] Hopefully our efforts have at least helped lay the groundwork for future discussion of the potential role of copyright in biotechnology. It took many years for the Copyright Office to evolve from its initial position of "profound doubt" regarding the copyrightability of software, and there is reason to believe that history might repeat itself with respect to EGC.

IV. Copyright Would Supplement Rather Than Supplant Patent for EGC

In the Denial, the Office asserted that one reason DNA should not be eligible for copyright is that it is already eligible for patent protection. But the patentability of EGC should really have no bearing on the question of copyrightability. As the Court of Appeals for the Federal Circuit recently

40. DNA 2.0, Inc., *Supplementary Document 2: Affirmance of Refusal for Registration*, 35 BIOTECHNOLOGY L. REP. 119 (2016).

41. *Id.*

42. *Id.*

43. Holman, Gustafsson & Torrance, *supra* note 30, at 103-11.

and unequivocally reaffirmed in *Oracle America, Inc. v. Google Inc.*, "[n]either the Copyright Statute nor any other says that because a thing is patentable it may not be copyrighted."[44] In *Oracle*, the Federal Circuit specifically addressed the question of whether copyright and patents could coexist in the context of software, but the same legal and policy considerations would apply to EGC. Patent and copyright could easily play complementary and synergistic roles in the protection of EGC, much as they currently do with respect to software. In fact, some degree of redundancy in intellectual property protection for such an important area of technology is desirable, as insurance in the event that one mode of protection ultimately proves less robust than was originally thought.

For example, consider the effect that the recent tightening of the patent eligibility standard has had on software patents. For years, prior to the Supreme Court's decision in *Bilski v. Kappos*,[45] the courts had been loosening the standard for patent eligibility, and the PTO responded by issuing a host of patents directed towards software inventions.[46] However, since the Court's recent imposition of a stricter standard, particularly through its decision in *Alice v. CLS Bank*,[47] we have seen a parade of previously issued software patents invalidated for failure to satisfy the new standard.[48] As a practical matter, the patent protection that software innovators thought they had achieved through patents, and which was the basis for investment in companies seeking to commercialize the technology, is proving to have been largely illusory. Fortunately, copyright for software remains a viable alternative, as was recently affirmed in *Oracle*, and provides at least a baseline level of protection for software developers, even as they are stripped of their patents. With respect to biotechnology, recent tightening of the patent eligibility requirement threatens to take a similar toll, particularly in certain areas, such as diagnostics.[49]

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44. 750 F.3d 1339, 1380 (Fed. Cir. 2014) (alteration in original) (citing Mazer v. Stein, 347 U.S. 201, 217 (1954)); *see Mazer*, 347 U.S. at 217 ("We do hold that the patentability of the statuettes, fitted as lamps or unfitted, does not bar copyright as works of art.").

45. Bilski v. Kappos, 561 U.S. 593 (2010).

46. Christopher M. Holman, *The Mayo Framework Is Bad for Your Health*, 23 GEO. MASON L. REV. 901, 904-06 (2016) [hereinafter Holman, *The Mayo Framework*].

47. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

48. Holman, *The Mayo Framework*, *supra* note 46, at 923-24; *see also* Robert R. Sachs, *The One Year Anniversary: The Aftermath of #AliceStorm*, BILSKIBLOG (June 20, 2015), http://www.bilskiblog.com/blog/2015/06/the-one-year-anniversary-the-aftermath-of-alice storm.html.

49. Holman, *The Mayo Framework*, *supra* note 46, at 923-24.

Unfortunately, because copyright has yet to be recognized for EGC, there is no backup in the event patents are taken away. The primary alternative form of intellectual property protection currently available for biotechnology is trade secret and, as has been explained elsewhere, there are substantial public policy concerns incident to shifting the emphasis of intellectual property and biotechnology from patents to trade secrets.[50] The availability of a viable copyright alternative for EGC could provide an important non-trade-secret baseline of protection in the face of continuing uncertainty with respect to the viability of patents in the context of engineered DNA and biotechnology.

At this point in the discussion, one might ask why it is that the law has developed in a manner such that software innovation is afforded the benefits of both copyright and patent protection, but biotechnological innovation is not. The answer probably has much to do with historical context. At the time copyright was initially opened up to computer programs, in the late 1970s and early 1980s, it was unclear whether patent protection would be available for software. In fact, the Supreme Court issued two decisions in the 1970s finding the computer programs at issue in those cases ineligible for patent protection.[51] This was problematic from an innovation-policy perspective, since it was widely recognized that some form of intellectual property for software innovation would be necessary to incentivize optimal innovation.[52] With the facial similarity of a transcribed computer program and traditional text, policymakers—and ultimately Congress and the courts—grasped upon the fiction that a computer program is a "literary work," and essentially enlisted copyright to fill the apparent intellectual property void.[53]

Soon after the copyrightability of computer programs was established, the Supreme Court held in *Diamond v. Diehr* that some computer programs are patent eligible,[54] and the Federal Circuit followed up with a series of decisions espousing a quite permissive standard for the patent eligibility of software.[55] As a result, both patents and copyright came to play substantial and non-redundant roles in protecting innovation in this important area of

50. John M. Conley, Robert Cook-Deegan & Gabriel Lázaro-Muñoz, *Myriad After* Myriad*: The Proprietary Data Dilemma*, 15 N.C. J.L. & TECH. 597, 600 (2014).

51. Parker v. Flook, 437 U.S. 584, 589-90 (1978); Gottschalk v. Benson, 409 U.S. 63, 73 (1972).

52. *See* Holman, *A Bellwether*, *supra* note 26, at 673-74.

53. Holman, *Copyright*, *supra* note 7, at 710.

54. Diamond v. Diehr, 450 U.S. 175, 191-92 (1981).

55. Holman, *The Mayo Framework*, *supra* note 46, at 905-06.

technology. In a like manner, synthetic biologists might choose to use copyright as a supplement to patent protection for some aspects of their inventions, thereby filling potential gaps in coverage that might arise when patent is the only form of intellectual property available. Alternatively, they might choose to rely on copyright in lieu of patent, thereby obviating some of the policy concerns associated with the patenting of genetic sequences in a manner that better facilitates open access and follow-on innovation.[56] Many of the advantages that flow from using copyright to protect software would also apply to EGC, as discussed in more detail below.[57]

There are those who argue that EGC does not meet the statutory requirements for copyrightability.[58] But it is important to recognize that essentially the same arguments have long been raised with respect to copyright for software, although in recent years it has become much less controversial. While today it is well settled that a computer program can be copyrighted as a "literary work,"[59] for years many experts in copyright law bridled at the suggestion.[60] Even after the copyrightability of software was generally accepted, courts struggled when applying judicial precedent, which has historically focused on the protection of aesthetic works, to functional computer programs.[61] Today, copyright protection for software is thoroughly entrenched, and it would be extremely difficult to retreat, particularly in view of the fact that Article 10 of the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS") provides that "[c]omputer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971)."[62] Nonetheless, as pointed out by the U.S. Solicitor General in an amicus brief recently filed with the Supreme Court recommending denial of certiorari in the case of *Google, Inc. v. Oracle America, Inc.*, the Supreme Court has yet to address

56. *See* Ledford, *supra* note 10, at 17.

57. *See infra* Part VI.

58. Holman, *Copyright*, *supra* note 7, at 704-05 (collecting sources).

59. 1 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 2.04[C][2] (Matthew Bender, rev. ed. 2013) [hereinafter NIMMER ON COPYRIGHT].

60. Samuelson, *supra* note 31, at 665-71; *see also* Leo J. Raskind, *The Uncertain Case for Special Legislation Protecting Computer Software*, 47 U. PITT. L. REV. 1131, 1143-44 (1986).

61. *See, e.g.*, Lotus Dev. Corp. v. Borland Int'l, Inc., 49 F.3d 807, 820 (1st Cir. 1995) (Boudin, J., concurring) ("Applying copyright law to computer programs is like assembling a jigsaw puzzle whose pieces do not quite fit.").

62. TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, pt. II, § 1, art. 10.1 (Apr. 15, 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

the application of copyright principles to computer programs, and so the exact contours of the protection are not entirely without ambiguity, particularly given certain splits between the various circuits.[63]

In applying copyright law and legal precedent to EGC, the close analogy between software and EGC is likely to prove invaluable. Many of the fundamental questions regarding the scope of copyright protection available to EGC, such as the degree of substantial similarity required to show non-literal infringement, the proper application of the idea/expression dichotomy, and related concepts such as merger, to name but a few, have already been addressed in numerous judicial decisions involving computer code.[64] These decisions often explicitly acknowledge that the traditional doctrines are used as policy levers, and that, particularly with respect to functional copyrighted works like software (and EGC would also fall within this category), it is extremely important to interpret long-standing doctrine in a manner that furthers innovation policy, recognizing that much of the precedent originated in cases involving primarily aesthetic works that do not implicate the same policy concerns.[65]

Fortunately, the law has a long and well-established tradition of using analogy as a primary mechanism for adapting to the development of new technologies that warrant copyright protection, and for doing so in a manner that remains cognizant of the overriding policy objectives underlying copyright law. Professor Nimmer has observed, for example, that

> [a]s to new forms of creative expression that may emerge in the future as a result of scientific discoveries or technological developments . . . [i]f such a new form is sufficiently analogous to the kinds of works that are expressly protected in the eight

63. Brief for the United States as Amicus Curiae, Google, Inc. v. Oracle Am., Inc., 135 S. Ct. 2887 (2016) (No. 14-410) (Mem.), 2015 WL 2457656 at *19-*23; *see also* Apple Compt., Inc. v. Franklin Comput. Corp., 714 F.2d 1240, 1253 (3d Cir. 1983) ("We believe that in the context before us, a program for an operating system, the line [between idea and expression] must be a pragmatic one, which also keeps in consideration 'the preservation of the balance between competition and protection reflected in the patent and copyright laws.'"); Comput. Assoc. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 711 (2d Cir. 1992) ("We are satisfied that the three step approach we have just outlined not only comports with, but advances the constitutional policies underlying the Copyright Act. Since any method that tries to distinguish idea from expression ultimately impacts on the scope of copyright protection afforded to a particular type of work, 'the line [it draws] must be a pragmatic one, which also keeps in consideration "the preservation of the balance between competition and protection . . . ."'" (alteration in original) (quoting *Apple Comput.*, 714 F.2d at 1253)).

64. *See infra* Part VI.

65. *See infra* Part VI.

> categories, it will be regarded as falling within "the present congressional intent," even though the similarity is only by analogy.[66]

Similarly, Professor Goldstein correctly observes in his treatise that

> the question will sometimes arise whether a new form of authorship, not expressly mentioned in the Act, is entitled to protection. The most practical and principled approach to this section is to reason by analogy to works expressly listed in section 102. . . . [N]ew forms of works should be protected if they are similar to those listed and not protected if they are dissimilar.[67]

V. Desired Policy Attributes of a Copyright Regime Encompassing EGC

In a 1988 article, Professor Dan Burk concluded that while EGC would probably qualify for copyright protection, at least as a matter of legal doctrine, such an extension should only occur if it would further public policy objectives.[68] He opined that, at the time when he wrote that article, which was relatively early in the biotechnology revolution, policy considerations did not seem to support the extension of copyright protection to genetic sequences, and for that reason he suggested that society refrain from going down that path.[69]

I agree that extending copyright to EGC should only be pursued if it makes sense as a matter of policy, but I would argue that, in fact, compelling policy objectives might be furthered by extending copyright to genetic sequences, and I believe the proposal warrants serious consideration. Of course, opinions will vary with respect to exactly what constitutes optimal innovation policy. Some would be in favor of very narrow and limited scope of protection, for example, whereas others would favor more robust rights. Ideally, copyright for engineered DNA would provide some baseline of protection that supplements and complements patent protection, but does not supplant it, just as patent and copyright exist side-by-side in the context of software.

The first policy issue to address concerns the manner in which copyright should treat human genes and other naturally occurring DNA sequences. I

66. 1 NIMMER ON COPYRIGHT, *supra* note 59, § 2.03[A].
67. 1 PAUL GOLDSTEIN, GOLDSTEIN ON COPYRIGHT § 2.6 (3d ed. 2016).
68. Burk, *supra* note 9, at 520-25.
69. *Id.*

have found that when I initially broach the idea of copyright for EGC to someone who has not previously given the idea much thought (most copyright scholars, for example), the initial response is typically an objection based on the idea that no one should be able to "own" another person's genes or, for that matter, genetic information in general. Indeed, a widespread resistance to the idea of property rights in human genes and genetic materials appears to have been a primary driver in the Supreme Court's decision to take the *Myriad* case and would likely be an obstacle in any move to extend copyright to DNA.[70]

A consensus position on optimal innovation policy would likely impose some sort of requirement that, in order to be copyrightable, a synthetic sequence must incorporate some non-trivial degree of variation relative to the closest naturally occurring counterpart. Thus, for example, the introduction of a very slight modification to a naturally occurring DNA sequence should generally not be sufficient to render that sequence copyrightable. In fact, some might argue that a relatively substantial degree of difference should be required as a prerequisite to copyright protection. In *Myriad*, the Supreme Court recently suggested that in order to be patent-eligible a chemical compound must be "markedly different" from any naturally occurring counterpart.[71] The "markedly different" standard was subsequently incorporated into PTO guidance on patent subject-matter eligibility.[72]

There are many dimensions in which an EGC can differ from a naturally occurring counterpart upon which it might be based. For example, due to the redundancy of the genetic code, a sequence encoding a native protein can be altered at the nucleotide level to generate an EGC that still codes for the identical protein sequence.[73] From a policy perspective, a single nucleotide alteration that results in a synonymous DNA sequence of this sort might be considered creatively insufficient to warrant copyright protection. On the other hand, multiple alterations, perhaps incorporated into the sequence in order to optimize codon usage for improved expression in a recombinant host, could be characterized as the sort of substantial and

70. *See The Fight to Take Back Our Genes*, ACLU, https://www.aclu.org/feature/fight-take-back-our-genes (last visited May 12, 2017).

71. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013).

72. 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618, 74,622-24 (2014).

73. *See generally* Holman, *Debunking*, *supra* note 20.

creative departure from nature that would warrant protection.[74] Alternatively, nucleotide alterations might be introduced that change the amino acid sequence of the encoded protein, which could result in functional differences ranging from subtle to extreme.[75] Possible permutations on these ideas are virtually infinite, but suffice it to say that optimized innovation policy might warrant the institution of a threshold for copyrightability that requires some substantial degree of divergence from the corresponding native sequence.

Synthetic biology encompasses not only engineered genes, but also engineered genetic systems, including engineered recombinations of genes and other genetic elements.[76] The individual genes and genetic elements, which can include promoters, enhancers, and other regulators of gene expression, can be thought of as modules.[77] Much like a software engineer can create new software by recombining modules of code, a genetic engineer can recombine genetic modules to achieve a desired outcome in an engineered biological system.[78] In either case, the modules themselves might already exist, but the creative reorganization and integration of preexisting modules can nonetheless represent a significant feat of engineering. Stanford University's Christina Smolke recently reported her laboratory's successful creation of a synthetic twenty-three-gene, opioid-synthesis pathway in a bacteria, and with advances in synthetic biology, even more complex synthetic genetic systems are surely on the horizon.[79]

The engineering of genetic modules can be quite simple - the earliest feats of genetic engineering, for example, typically involved the introduction of a single, cloned gene into a recombinant plasmid.[80] But with advances in synthetic biology, the rearrangement of genetic elements is becoming quite complex, and is resulting in synthetic biology products that comprise a large number of interacting modules designed to achieve a complex result.[81] The Smolke group's introduction of a new metabolic

74. For example, this technique is used in codon optimization. *See generally* Natalie J. Ward et al., *Codon Optimization of Human Factor VIII cDNAs Leads to High-Level Expression*, 117 BLOOD J. 798 (2011).

75. Holman, *Debunking*, *supra* note 20, at 242.

76. Holman, *Developments*, *supra* note 2, at 419-22.

77. *See id.* at 438-39.

78. *Id.* at 421.

79. Stephanie Galanie et al., *Complete Biosynthesis of Opioids in Yeast*, 349 SCIENCE 1095 (2015).

80. Holman, *Developments*, *supra* note 2, at 397.

81. *Id.*

pathway into an engineered microorganism is a good example.[82] Optimal innovation policy could dictate some substantial threshold of complexity and creativity in the reordering of existing genetic modules as a prerequisite to copyright protection.

To the extent possible, copyright for EGC should provide the necessary scope of coverage to incentivize innovation without unduly impeding subsequent research and innovation by others.[83] Copyright protection that would prevent outright pirating, i.e., the direct appropriation of the identical DNA sequence, would be highly desirable, particularly as it is becoming increasingly cheap and easy to generate an unlimited number of exact copies of a DNA sequence. Replication of EGC embodied in a seed can be particularly easy - in some cases requiring nothing more than soil, water, and sunlight.[84] Access to engineered DNA is no longer required for copying, since a genetic sequence published online can readily be converted into the equivalent DNA molecule, and then used to produce additional copies *ad infinitum*.[85] Furthermore, some reasonable scope of protection would be desirable in order to deter an unscrupulous copyist from skirting infringement by simply introducing a few minor changes to a copyrighted DNA sequence.[86] At the same time, many would argue that the protection should be tailored so as not to unduly preclude others from independently creating EGC that provides substantially similar functionality.

If copyright is extended to EGC, it should be done in a manner that minimizes the threat of liability for primarily non-commercial actors, such as academic researchers, educators and their students, and synthetic biology hobbyists (i.e., DIY synthetic biologists). Patent law has a very limited exemption for research use, and this lack of an explicit safe harbor for research is a focal point of criticism of the patent system.[87] An optimized copyright regime for EGC might provide a relatively broad exemption for a wide variety of research, facilitating follow-on innovation while at the same time addressing the concerns of critics.

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82. *See generally* Galanie et al., *supra* note 79 (describing process).

83. *See* Holman, *Developments*, *supra* note 2, at 458-62; *see also* Heidi Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 J. POL. ECON. 1, 24-25 (2013).

84. Holman, *A Bellwether*, *supra* note 26, at 669-70.

85. *Id.*

86. *See id.*

87. *See generally* Joshua D. Sarnoff & Christopher M. Holman, *Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents*, 23 BERKELEY TECH. L.J. 1299 (2008).

In the realm of software, the open-source-software movement has leveraged copyright protection to promote sharing and public accessibility of software code in a manner that facilitates collaborative innovation.[88] For years there has been a significant and growing interest in developing an open-source alternative for biotechnology.[89] Given the increasing convergence of software design and biotechnology, particularly in the realm of synthetic biology, it is not surprising that biotechnologists yearn for the perceived benefits of open source. Unfortunately, although there have been earnest attempts at open-source biotechnology, up to this point we have not seen a truly workable model that compares with what exists for software.[90] Optimally, a copyright regime encompassing EGC would facilitate the development of a pragmatically viable open-source alternative for biotechnology.

Interoperability is often a critical consideration in software design and development, and has been defined as the "[a]bility of a computer system to run application programs from different vendors, and to interact with other computers across local or wide-area networks regardless of their physical architecture and operating systems."[91] Similarly, there has been an increasing recognition of a need for interoperability in synthetic biology.[92] A copyright regime that facilitates interoperability should be considered as an important policy objective.

Synthetic biologists complain that patents can be prohibitively expensive to acquire and that they can take too long to issue, particularly for a fast-

88. *See* MICHAEL A. CUSUMANO, THE BUSINESS OF SOFTWARE: WHAT EVERY MANAGER, PROGRAMMER AND ENTREPRENEUR MUST KNOW TO THRIVE AND SURVIVE IN GOOD TIMES AND BAD 124-25 (2004); Ronald J. Mann, *Commercializing Open Source Software: Do Property Rights Still Matter?*, 20 HARV. J.L. & TECH. 1, 21-22 (2006).

89. Ethan R. Fitzpatrick, *Open Source Synthetic Biology: Problems and Solutions*, 42 SEATON HALL L. REV. 1363, 1370-78 (2013); Bryn Nelson, *Cultural Divide*, 509 NATURE 152, 152-53 (2014); Torrance, *Synthesizing Law*, *supra* note 9, at 653-58; *see also* Holman, *Developments*, *supra* note 2, at 437-42; Ledford, *supra* note 10, at 16.

90. Sam Finegold, *The Hard Path to Open Source Bioinnovation: How Cambia Is Strengthening the Agricultural Open Source Infrastructure*, SCI. PROGRESS (Aug. 20, 2012), http://scienceprogress.org/2012/08/the-hard-path-to-open-source-bioinnovation/ ("[D]espite the ambitious aspirations, BioForge was shut down after just three years. . . . The nature of biotechnology poses additional barriers to it operating on an open-source model.").

91. *Interoperability*, BUSINESSDICTIONARY, http://www.businessdictionary.com/definition/interoperability.html#ixzz3jNBhKdSe (last visited May 12, 2017).

92. Jorge Contreras, Arti K. Rai & Andrew W. Torrance, *Intellectual Property Issues and Synthetic Biology Standards*, 33 NATURE BIOTECHNOLOGY 24 (2015); Kristian M. Müller & Katja M. Arndt, *Standardization in Synthetic Biology*, 813 METHODS IN MOLECULAR BIOLOGY 23, 39-40 (2012).

moving company like ATUM.[93] Compounding the problem is the uncertainty regarding the scope of patentable subject matter, exacerbated by recent Supreme Court decisions such as *Mayo* and *Myriad*. The long-time lag between applying for a patent and issuance of a patent was not such a problem for the original products of biotechnology— pharmaceuticals and genetically engineered agricultural products—because these products took many years to bring to market, largely due to stringent regulatory requirements.[94] With advances in synthetic biology, however, the commercialization of new synthetic biology innovations can occur quite rapidly, often on a time scale much shorter than the time necessary to obtain a patent.[95] Furthermore, the exploding number of engineered genetic sequences being developed is rendering it prohibitively expensive to seek patent protection for each one individually.[96] The democratization of synthetic biology, including the DIY-synthetic-biology movement, will likely contribute to a demand for intellectual property protection that is easier and less expensive to obtain than patent protection, and copyright could be particularly advantageous in this regard.[97] Thus, an optimal copyright regime will provide a much quicker, less expensive, and easier form of intellectual property relative to patents.

It would also be desirable to have a form of intellectual property available for engineered DNA that would promote early public disclosure. Because of the time and money necessary to file for a patent and the problems associated with public disclosure prior to securing patent protection, the patent regime fosters an environment that can incentivize inventors to delay disclosure.[98] The recent heightening of the requirements of patent eligibility and the attendant uncertainty as to whether patent protection will be available for many gene-based inventions are reportedly pushing some companies toward maintaining genetic sequence information as a trade secret.[99] A copyright regime that provides a reasonable baseline level of protection at an early stage could promote more public disclosure, which many would see as a desired policy objective.

Ideally, copyright for EGC would provide effective protection not only for the code itself, but also for the commercial products utilizing the EGC.

93. Holman, *Developments*, *supra* note 2, at 445-46; Ledford, *supra* note 10, at 16.
94. Holman, *Developments*, *supra* note 2, at 445-46.
95. *Id.* at 425, 445.
96. *Id.* at 444-45.
97. *Id.* at 454.
98. *Id.* at 444-47
99. Conley, Cook-Deegan & Lázaro-Muñoz, *supra* note 50, 599-600.

First and foremost, an effective copyright regime would provide the ability to protect genetically modified seeds. So far, patents have proven reasonably effective in protecting the genetically modified crops developed by companies such as Monsanto and DuPont, but there are significant limitations in the effectiveness of using patents in this regard.[100] Genetically engineered seeds raise concerns about misappropriation and free-riding similar to those raised by software and digitally recorded music, in that it is extremely easy for end-users of these technologies to reproduce and distribute a virtually unlimited number of identical copies.[101] In the case of software and digitally recorded music, reproduction and distribution occurs on the computer and over the Internet, whereas with respect to agriculture it occurs in a farmer's fields, but the underlying policy concerns are the same.

While today genetically modified seeds are the form of biotechnological innovation with the most problematic potential for replication by end-users, in the future, a host of other non-agricultural synthetic biology products will, in all likelihood, raise similar concerns.[102] Thus, it is important that any copyright regime that develops for EGC can be effectively leveraged to protect self-replicating synthetic biology products from misappropriation, including, but not limited to, seeds.

The practical enforceability of copyright will likewise be an important consideration. A copyright regime encompassing EGC will optimally be structured in a manner that renders enforcement against infringers more efficient and/or provides more effective remedies.

Ideally, copyright for EGC will avoid the problem of potential inadvertent infringement, an issue that came to the forefront a few years ago when the Supreme Court decided *Bowman v. Monsanto Co.*[103] The defendant, Vernon Bowman, was a farmer who argued that sale of a patented seed should exhaust all patent rights in second-generation seeds.[104] Supporters of Bowman argued that without patent exhaustion, farmers faced the threat of virtually unavoidable liability for inadvertent infringement caused, for example, by second-generation seeds blown from another field or purchased from a seed vendor.[105] The Supreme Court rejected Bowman's argument in this particular case, finding that Bowman's

100. *See generally* Holman, *A Bellwether*, *supra* note 26 (discussing patent protection for genetically modified seeds).

101. *Id.* at 669-670, 674, 678.

102. Holman, *Developments*, *supra* note 2, at 451-53.

103. 133 S. Ct. 1761, 2768-69 (2013).

104. *Id.* at 1766.

105. *See id.* at 1768-69; Holman, *A Bellwether*, *supra* note 26, at 684-86.

actions were knowing and purposeful and thus the antithesis of inadvertent.[106] The Court did recognize, however, that inadvertent infringement could constitute a substantial policy concerns, and it left the door open to address those concerns in a later case presenting such facts.[107] The potential for inadvertent infringement is a general concern with respect to many DNA-based inventions, such as recombinant seeds, and a copyright regime for EGC would optimally be structured in a manner that would shield truly inadvertent infringers from liability.[108]

Many would also argue that copyright should provide some form of safe harbor from liability for certain entities involved in the production of engineered DNA. For example, companies such as ATUM that provide DNA synthesis as a service for customers are currently not in a good position to confirm whether a sequence ordered by a customer could potentially result in charges of patent infringement.[109] Similarly, non-profits like Biobricks are hesitant to provide DNA components to commercial entities for fear of patent infringement liability.[110] Ideally, a copyright regime for engineered DNA would be structured such that it facilitates relatively painless freedom-to-operate clearance, and/or provides some form of protection from liability for third-party contractors and other intermediaries with respect to which an imposition of liability would create public policy concerns.

Finally, one of the arguments that is most often raised against extending copyright to EGC is the duration of the copyright term. Many would argue that the patent term is already too long, at least for the purposes of synthetic biology, and worry about creating a new form of intellectual property protection that lasts much longer than a patent. If these concerns regarding the long duration of copyright could be addressed, it seems likely that much of the opposition to the use of copyright in biotechnology would dissipate.

VI. Applying Copyright Doctrine to EGC as a Policy Lever

Ideally, copyright should treat EGC in a manner that provides the optimal degree of protection while preventing overprotection that could effectively tie up the building blocks of future innovation. This Part VI considers how some of the established features of copyright law could be

106. *Bowman*, 133 S. Ct. at 1769.
107. *See id.*
108. *See* Holman, *A Bellwether*, *supra* note 26, at 697-716.
109. *See supra* Part II.
110. *See* Holman, *Developments*, *supra* note 2, at 447-49.

interpreted and applied as policy levers to achieve some of the desired policy objectives outlined above.

A. Copyright Duration

In a previous article, I explained that many of the arguments raised against copyright for EGC are based on fundamental misunderstandings of copyright law and/or the nature of EGC.[111] One of the objections that I have heard voiced repeatedly, however, is legitimate: Copyright simply lasts too long - sometimes more than a century, depending on factors such as lifespan of the author.[112] There are those who believe that even the much shorter patent term is too long for biotechnology and that the last thing we need is a thicket of copyrights constraining the freedom of operation for future generations of synthetic biologists. One might also argue that the long duration of copyright is gratuitous and not necessary to incentivize the creation of new EGCs.

My response to this concern is three-fold. First, I agree that the duration of copyright is probably longer than necessary for EGC (and also, by the way, for computer programs for much the same reasons), and it might make sense for Congress to consider enacting a subject-matter-specific reduction in duration for copyright covering EGC or even copyright in general. Second, short of reducing the copyright term, Congress could, and probably should, consider statutory reforms that would address some of the underlying concerns associated with the duration of the copyright term. Third, and perhaps most crucial, it is important to recognize that the long copyright term is already in force with respect to computer software and does not appear to have created substantial impediments to follow-on innovation in that technological space. There is no reason to think it will be any more problematic in the context of EGC.

1. Reduction of Copyright Duration

Although some argue that the current copyright term is too long and should be reduced, as a practical matter this seems unlikely, at least in the near term, in part because of international treaty obligations.[113] A subject-

111. Holman, *Copyright*, *supra* note 7, at 722, 730.

112. Ledford, *supra* note 10, at 17 (noting that Stanford Professor Drew Endy "worries about the duration of copyright protections, which can last up to 120 years; patents, by contrast, expire after 20").

113. TRIPS provides that "[c]omputer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971)." TRIPS, *supra* note 62, at pt. II, § 1, art. 10.1.

matter-specific reduction in copyright term, however, might be more feasible and worth consideration. There would be some precedent for this approach. Many countries already afford a shorter term of protection to sound recordings, and it has been suggested that the United States should adopt a similar approach.[114] The Copyright Statute provides *sui generis* forms of copyright-like protection for semiconductor chips and boat hulls, and the duration of these protections is only ten years.[115] Along similar lines, Congress has also considered copyright-like protection for fashion designs, which would have a very short duration, but this protection has yet to be enacted.[116]

Thus, it would not be entirely out of the question to address the duration concern by congressional action, either by specifically shortening the duration of copyright for EGC or, perhaps, by creating *sui generis* copyright-like protection for EGC. At least one commentator has advocated for an extension of *sui generis* copyright-like protection to EGC (as well as software and nanotechnology).[117] If a *sui generis* approach is taken, it could provide more flexibility to address other concerns that have been expressed with regard to extending copyright to engineered DNA. Any *sui generis* protection should ideally incorporate the beneficial features of copyright as identified in this article. The duration of protection for EGC should be tailored to meet the needs of the synthetic biology community and likely would be substantially longer than the short period that is being contemplated for fashion design, for example.

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114. Tim Brooks, *Only in America: The Unique Status of Sound Recordings Under U.S. Copyright Law and How It Threatens Our Audio Heritage*, 27 AM. MUSIC 125, 128 (2009) ("All countries except the United States recognize that recordings are derivative works and accord them shorter terms of protection than for the music or text they embody.").

115. Semiconductor Chip Protection Act of 1984 § 302, 17 U.S.C. § 901-14 (2012); Vessel Hull Design Protection Act § 502, 17 U.S.C. § 1301-32 (2012) (boat hull designs receive protection upon registration with the Copyright Office with the protection lasting for ten years after registration).

116. The Design Piracy Prohibition Act, H.R. 2196, 111th Cong. (2009), and the Innovative Design Protection and Piracy Prevention Act, S. 3728, 111th Cong. (2010), would have provided three years of protection for fashion designs.

117. *See* Dennis S. Karjala, Protecting Innovation in Computer Software, Biotechnology, and Nanotechnology 31 (Mar. 12, 2010) (unpublished manuscript), http://works.bepress.com/dennis_karjala/4 (arguing that *sui generis*, copyright-like protection would be better suited to software, biotechnology, and nanotechnology than copyright).

2. Statutory Reforms Addressing Underlying Concerns

Alternatively, Congress could amend the statute in a manner that renders the long duration of copyright less objectionable. For example, some commentators have suggested that the long duration of copyright exacerbates the so-called "orphan works" problem, but there are avenues for attenuating these concerns that do not require any modification of the copyright term.[118] A group calling itself the Copyright Principles Project ("CPP") recently suggested that problems associated with the long duration of copyright could be addressed by re-formalizing copyright law, and in particular by creating stronger incentives for copyright registration, thereby making it easier for follow-on creators to identify the owners of copyrighted works and to seek permission to use the work.[119] The CPP's proposed incentives for registration include ideas such as providing broader scope of fair use for unregistered works, denying protection against non-literal copying to unregistered works (while maintaining the right for the owner of an unregistered work to sue for literal copying), and broader exemptions for non-commercial use of an unregistered work.[120] These proposals could be adopted for copyright law in general or more specifically for EGC in order to address concerns associated with this proposed new category of copyrighted work.

The CPP also proposed expanding the use of private registry regimes to better enable follow-on creators to identify and seek licenses from rights owners.[121] The private registries envisioned by the CPP, which would be analogous to existing rights management organizations such as ASCAP, BMI, and the Copyright Clearance Center, could go a long way in addressing concerns associated with long duration of copyright.[122] A private registry could be particularly helpful in the case of EGC, because although the Copyright Office currently has no expertise in biotechnology or genetic

118. David R. Hansen et al., *Solving the Orphan Works Problem for the United States*, 37 COLUM. J.L. & ARTS 1, 12 (2013). "Orphan works" are works with respect to which the rights holder cannot be located even after a reasonably diligent search. Chris Castle & Amy E. Mitchell, *Orphan Works Legislation*, 71 TEX. B.J. 744, 745 (2008)

119. Pamela Samuelson et al., *The Copyright Principles Project: Directions for Reform*, 25 BERKELEY TECH. L.J. 1175, 1199 (2010). The CPP describes itself as comprised of twenty people having "various kinds of expertise and experience with copyright law and policy. . . . [including] law professors, lawyers from private practice, and lawyers for copyright industry firms." *Id.* at 1176.

120. *Id.* at 1201.

121. *Id.* at 1203-05.

122. *Id.*

sequences, there are a variety of private firms that have advanced capabilities for cataloging and searching genetic sequences.[123] Other governmental agencies, such as the PTO, which has years of experience dealing with property rights in genetic sequences, might also assist in registration and providing public notice of the existence of copyright in a particular EGC sequence. As the CPP noted, commercial databases operated by private entities such as Corbis and Getty have been established to facilitate rights clearance in the context of photographs,[124] and private prophylactics against orphan-work problems in the context of EGC would no doubt arise once there is sufficient demand.

The Copyright Office issued a report recommending that Congress address orphan works by providing a defense for those who, after diligent search, are unable to identify the owner of a work and who then proceed to incorporate that work into their own.[125] If Congress were to adopt such an approach, it could mitigate much of the potential negative impact of EGC copyright on follow-on innovation.

The CCP also suggested that Congress create a statutory provision that would facilitate the ability of authors to dedicate their works to the public domain.[126] This could be a particularly attractive option for EGC. In fact, it could become the norm for academic researchers, and many companies, such as ATUM, would likely find that it makes commercial sense to dedicate at least some of their EGC to the public domain. Publicly funded institutions, such as the National Institutes of Health, could even make this a requirement for funding or treat it as a favorable factor when considering approval of a grant application.

3. Copyright Generally Creates Narrower Rights Than Patent

When people voice concern about the long duration of copyright and worry about the effect of EGC copyright on subsequent innovation, they often seem to be equating copyright with the much broader rights associated with patents. For a variety of reasons, copyright is a much narrower form of protection with much less potential to negatively impact follow-on innovation. This probably goes a long way in explaining why the

123. *See, e.g.*, GQ LIFE SCI., https://www.gqlifesciences.com/(last visited May 12, 2017).

124. Samuelson et al., *supra* note 119, at 1203; *see also Rights and Clearance Services*, GETTYIMAGES, http://www.gettyimages.com/resources/rights-and-clearance-services (last visited May 12, 2017).

125. U.S. COPYRIGHT OFFICE, REPORT ON ORPHAN WORKS 95-96 (2006), http://www.copyright.gov/orphan/orphan-report.pdf.

126. Samuelson et al., *supra* note 119, at 1227.

long copyright term has not proven particularly problematic with respect to follow-on innovation in software. As discussed later in this article, for example, copyright should not prevent others from designing alternative EGC to carry out identical functions.[127] To help alleviate concerns, independent creation should never constitute copyright infringement, and naturally occurring DNA sequences and EGC that is substantially similar to naturally occurring DNA sequences should not be copyrightable.[128] Furthermore, the legal availability of fair use and other limitations on copyright similarly should ameliorate many of the objections premised upon the long duration of copyright.[129]

B. The Requirements of Copyrightability

Extending copyright to EGC does not imply that all EGC would be copyrighted. There are a variety of requirements of copyrightability that would preclude copyright protection for a subset of EGC; genetic sequences that too closely resemble naturally occurring genetic sequences, for example, may be excluded. These requirements of copyrightability could be interpreted and applied in the context of EGC in a manner designed to further public policy. As explained in this Part VI, the courts have repeatedly interpreted the doctrines of copyrightability in the context of software in a manner designed to achieve certain policy objectives associated with software innovation and, given the close analogy between EGC and computer code, these decisions could provide useful precedent in charting the course for a policy-driven interpretation of copyright doctrine in the context of EGC.

1. The Originality Threshold

As set forth by the Supreme Court in *Feist Publications, Inc. v. Rural Telephone Services Co.*, the threshold requirement for copyrightability is "originality."[130] In order to meet the threshold, a work must have been "independently created by the author (as opposed to copied from other works)" and must "possess[] at least some minimal degree of creativity."[131] Both prongs of the *Feist* test could provide meaningful restrictions on the scope of copyright protection available to EGC, requiring a certain degree

127. *See infra* Section VI.C.2.
128. *See infra* Section VI.B.4.
129. *See infra* Section VI.C.5.
130. 499 U.S. 340, 345 (1991); *see also* 17 U.S.C. § 102(a) (2012).
131. *Feist*, 499 U.S. at 345.

of creativity and effectively excluding sequences that come too close to a naturally occurring genetic sequence.

Of particular relevance in the context of DNA, the independent-creation requirement could be leveraged to effectively preclude copyright protection for any DNA sequence derived from a natural source. As discussed above, many of the objections raised with respect to extending copyright to DNA have focused on concerns that it would create property rights over human genes and other naturally occurring genetic material.[132] A strictly construed requirement of originality would address these concerns.

On the other hand, EGC should often be found to satisfy an independent-creation test, perhaps even in cases where it is quite similar to a naturally occurring genetic sequence. The Supreme Court recognized the creativity of genetic engineering in *Myriad*, noting that the "lab technician unquestionably creates something new when cDNA ["synthetically created" DNA] is made."[133] The fact that a synthetic biologist uses information about a naturally occurring sequence as the raw material in the creation of an original engineered genetic sequence should no more be a bar to copyright protection than would be the incorporation of knowledge gleaned from the natural world into a computer program. For that matter, a book based on historical facts can be copyrighted, even though the historical facts themselves were not created by the author. Likewise, a sculptor does not forfeit copyright protection by using naturally occurring wood or stone as his starting material. It makes little sense to suggest that a work cannot receive copyright protection simply because it is based to some extent on a product of nature, so long as it meets the modicum-of-creativity standard required under *Feist*.

The modicum-of-creativity prong of the *Feist* test[134] could draw the line between unprotectable natural sequences and copyrightable engineered sequences and thereby serve as a policy lever to further innovation policy. For example, it could be used to set a certain minimal requirement of divergence from nature by requiring as a prerequisite for copyright that an engineered DNA sequence incorporate a substantial departure from any corresponding natural sequence. This would mirror the PTO's current standard for patent eligibility of DNA sequences dictated by *Myriad*, pursuant to which a DNA sequence must be "markedly different" from a

132. *See supra* notes 70-75 and accompanying text.

133. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013).

134. *Feist*, 499 U.S. at 345.

naturally occurring counterpart in order to constitute patentable subject matter under 35 U.S.C. § 101.[135]

In fact, the extent to which EGC must diverge from nature in order to satisfy the modicum-of-creativity standard could actually be higher than the standard for patent eligibility set forth in *Myriad*. In *Myriad*, the Court held that BRCA cDNA is different enough from its natural counterpart to be patent-eligible, in spite of the fact that a cDNA sequence is extremely similar in both function and structure to the mRNA molecule on which it is based.[136] The cDNA embodies the same information as the corresponding mRNA, and there is really no creativity, at least in the literal sense, involved in converting naturally occurring mRNA into cDNA.[137] In my view, cDNA would generally not satisfy the originality requirement of copyright, even though the Supreme Court has deemed it patentable.

The requirement of creativity has, on occasion, been invoked to deny copyright protection to conventional literary works, creating precedent for courts to take an analogous approach when faced with an insufficiently creative EGC. In *Donald v. Zack Meyer's T.V. Sales & Service*, for example, a "common legal form" was declared uncopyrightable, based on the court's finding that "[t]he plaintiff did no original legal research which resulted in a significant addition to the standard conventional sales contract or chattel mortgage forms; he merely made trivial word changes by combining various forms and servilely imitating the already stereotyped language found therein."[138] In contrast, courts have found more elaborate blank forms evidencing greater creativity to meet the threshold.[139] In *Edwin K. Williams & Co. v. Edwin K. Williams & Co.-East*, for example, the court found the relatively more complex forms at issue in that case "constituted an integrated work entitled to copyright protection."[140] Similarly, in *Baldwin Cooke Co. v. Keith Clark, Inc.*, the court found an "Executive Planner" copyrightable as a compilation, distinguishing earlier cases that had found similar products uncopyrightable because "[n]one of the works

135. *See Myriad*, 133 S. Ct. at 2117, 2119.

136. *Id.* at 2116; *see* Brief of Amicus Curiae Law Professor Christopher M. Holman in Support of Neither Party, Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2884112, at *9-*12 [hereinafter Holman Amici Brief].

137. Holman Amici Brief, *supra* note 136, at *9.

138. 426 F.2d 1027, 1028, 1030 (5th Cir. 1970); *see also* Donald v. Uarco Bus. Forms, 344 F. Supp. 338 (W.D. Ark. 1972), *aff'd*, 478 F.2d 764 (8th Cir. 1973).

139. *See* Edwin K. Williams & Co. v. Edwin K. Williams & Co.-East, 542 F.2d 1053 (9th Cir. 1976); Baldwin Cooke Co. V. Keith Clark, Inc., 383 F. Supp. 650 (N.D. Ill. 1974).

140. *Edwin K. Williams & Co.*, 542 F.2d at 1061.

involved in those cases approached sophistication and complexity of format and arrangement involved here."[141]

As a general matter, the recombination of naturally occurring DNA sequences should be found to constitute a work deserving of copyright protection, but the requirement of creativity could be leveraged to ensure that a copyrightable design reflects some threshold level of creativity. For example, a very straightforward and routine operation—like splicing a commonly used promoter with a protein-encoding gene sequence—should probably be considered insufficiently creative to meet the standard.

It is well established that copyrightable expression can arise solely from the creative selection and arrangement of otherwise uncopyrightable elements. For example, in *Feist*, the Supreme Court held that the selection and arrangement of facts can be copyrightable, so long as the selection and arrangement evidences the necessary modicum of creativity.[142] Analogously, a creative selection and arrangement of naturally occurring genetic sequences in an engineered construct should be sufficient to warrant copyright protection for the construct. Significantly, the protection would not extend to the underlying facts, i.e., the naturally occurring sequence elements, and the selection and arrangement of the components would have to satisfy some minimal threshold of creativity.[143]

On the other hand, an insufficiently creative selection and arrangement of naturally occurring genetic sequences should be found to lack the necessary modicum of creativity to receive protection. Note, however, that the amount of creativity required under *Feist* has generally been interpreted as minimal[144] and, if the same standard is applied to EGC, many works involving the selection and arrangement of preexisting genetic elements would be deemed copyrightable, given the large and growing number of genetic sequences available for recombination. For example, a cDNA sequence corresponding exactly to a naturally occurring mRNA probably lacks the necessary creativity, but incorporating that cDNA sequence into a plasmid would probably involve sufficient creativity of expression, given that there are a large number of plasmids from which to choose and different locations and orientations in which the cDNA could be introduced into the plasmid. In the context of software, a novel arrangement of

141. *Baldwin Cooke Co.*, 383 F. Supp. at 650.

142. Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 345-46 (1991).

143. *Id.*

144. *See* N.Y. Mercantile Exch., Inc. v. IntercontinentalExchange, Inc., 497 F.3d 109, 119-20 (2d Cir. 2007) (Hall, J., concurring).

modules providing structure for a software program has been found to satisfy the creativity standard for originality.[145]

Of course, courts could ratchet up the modicum-of-creativity standard for EGC in furtherance of innovation policy.

One might argue that since the design of EGC is informed and guided in large part by the cumulative knowledge of the relationship between biological sequence and function, gleaned from observation of naturally occurring genetic sequences, these engineered sequences should generally fail the modicum-of-creativity test. But many works currently recognized as copyrightable, such as books describing natural phenomena or computer software incorporating fundamental principles of math and science, are based in part upon the observation of the natural world and naturally occurring phenomena, yet no one seriously suggests that the incorporation of this sort of knowledge renders the product uncopyrightable. Engineered genetic sequences are products of the design and intent of the creator, and the fact that starting materials and design principles are based in large part on the observation of naturally occurring sequences should not, as a general matter, render these products of creativity uncopyrightable.

The principle that copyright is not necessarily precluded for creative works that are based upon, or even highly similar to, uncopyrightable works of nature is illustrated by a recent district court decision overturning a Copyright Office decision to deny registration of "rock and stone sculptures that are used to make decorative concrete stamps."[146] The Office's decision that these man-made sculptures are not copyrightable was based on its improper conclusion that the sculptures were mere "slavish copies of uncopyrightable objects and, as such, do not contain a sufficient amount of original authorship to support copyright claims."[147] In particular, the Office "opined that the works are slavish copies because they just replicate natural stones and their features."[148] Although no one would dispute that naturally occurring stones and rocks are not copyrightable, the court pointed out that the sculptures at issue in this case "are not molds of existing stones or

145. Comput. Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693 (2d Cir. 1982); *see also* Oracle Am., Inc. v. Google Inc., 750 F.3d 1339 (Fed. Cir. 2014).

146. *See* Proline Concrete Tools, Inc. v. Dennis, No. 07CV2310-LAB AJB, 2012 WL 2886953, at *1 (S.D. Cal. July 13, 2012), *vacated on reconsideration*, 2013 WL 12116134 (S.D. Cal. Mar. 28, 2013). This decision was later vacated on procedural grounds. *See* Proline Concrete Tools, Inc. v. Dennis, No. 07CV2310-LAB AJB, 2013 WL 12116134, at *6 (S.D. Cal. Mar. 28, 2013).

147. *Proline*, No. 07CV2310-LAB AJB, 2012 WL 2886953, at *2 (citation omitted).

148. *Id.*

rocks. They are created from the artists [sic] interpretation of stones and rocks he has observed."[149] The court criticized the Office's decision not to register the stone sculptures, noting that it seemed "to result from its confusion over how [the registrant] creates the sculptures and what exactly it seeks to copyright."[150]

For essentially the same reason, the Copyright Office's current position that EGC is not copyrightable because it is based on naturally occurring genetic sequences suggests that the Copyright Office is confused as to this distinction between naturally occurring genetic code and engineered genetic code. Perhaps the only relevant difference between EGC and the sculptures in *Proline* is that the question of copyright for EGC has yet to make it to the courts.

Some judicial opinions seem to suggest that a heightened requirement of creativity exists with respect to derivative works, as compared to truly original works.[151] A recent Eleventh Circuit Court of Appeals decision, *Home Legend, LLC v. Mannington Mills, Inc.*, is particularly on point.[152] In *Home Legend*, an alleged copyright infringer brought an action against the copyright owner seeking a declaratory judgment that its copyright for a laminate-flooring design was invalid because the flooring design was nothing more than a "slavish copy of nature."[153] The court rejected this argument for reasons similar to those of the court in *Proline*, holding that the flooring design was not a slavish copy of nature, but rather the expression of a sufficiently creative idea to be protectable by copyright.[154] The court did, however, go on to characterize the flooring design as a derivative work, given that its design "reflects the uncopyrightable features of each plank—features like the shape of the natural underlying wood grain and the plank's shape, both of which are in the public domain."[155] As a derivative work, the court held that the laminated flooring design was

149. *Id.* (citation omitted).

150. *Id.* at *3.

151. *See, e.g.*, Gracen v. Bradford Exch., 698 F.2d 300, 305 (7th Cir. 1983). *But see* Schrock v. Learning Curve Int'l, Inc., 586 F.3d 513, 516 (7th Cir. 2009) ("*Gracen* said that 'a derivative work must be substantially different from the underlying work to be copyrightable.' This statement should not be understood to require a heightened standard of originality for copyright in a derivative work." (internal citation omitted)).

152. 784 F.3d 1404, 1414 (11th Cir. 2015) (citing Warren Publ'g, Inc. v. Microdos Data Corp., 115 F.3d 1509, 1515 n.16 (11th Cir. 1997) ("A creative work is entitled to the most protection, followed by a derivative work, and finally by a compilation.")).

153. *Id.* at 1410.

154. *Id.* at 1414.

155. *Id.*

eligible for only relatively narrow copyright protection, limited to "identical and near-identical copies."[156]

Similarly, an engineered DNA sequence that is based on a naturally occurring DNA sequence could be plausibly characterized as derivative of the native sequence and, hence, potentially subject to a heightened requirement of creativity. Even if this requirement is satisfied, derivation from a naturally occurring sequence could result in narrow coverage limited to identical or near-identical sequences. This approach could serve a policy objective of increasing the minimum creativity threshold for engineered DNA, thereby excluding from copyright protection DNA sequences lacking some requisite degree of creativity and providing only narrow protection for minimally creative sequences. On the other hand, the more EGC departs from nature and other public domain genetic sequences, the more it should be afforded the more robust protection generally available for copyrighted works.

2. Fixation in a Tangible Medium

Unlike patent protection, which must be specifically applied for and granted by the PTO, copyright comes into existence at the time of fixation in a tangible medium of expression.[157] This low barrier to protection could provide a number of policy benefits. For example, it would greatly reduce the cost, effort, and time associated with securing intellectual property protection for EGC and associated biotechnological products, such as recombinant seeds. The Report of the National Commission on New Technological Uses of Copyrighted Works ("CONTU") specifically recognized this as one of the benefits of extending copyright protection to software, predicting that, because copyright exists from the moment a work is fixed, "copyright is likely to be increasingly important in protecting computer programs, particularly those of small entrepreneurs who create their works for individual consumers and can neither afford or properly use other forms of protection."[158]

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156. *Id.*

157. 17 U.S.C. § 102(a) (2012).

158. NATIONAL COMM'N ON NEW TECHNOLOGICAL USES OF COPYRIGHTED WORKS, FINAL REPORT at 15 (1978) [hereinafter "CONTU Report"]. Congress established CONTU in the 1970s to study and make recommendations as to how the copyright law should respond to various technological developments, most notably the increasing significance of computer programs. *See id.* at 1. The commission was specifically directed to consider and make recommendations with respect to the question of whether, and to what extent, computer programs could be protected under current copyright law and whether copyright law should be amended to accommodate computer programs. *See id.* CONTU issued its highly

The ease with which the requirement of fixation is satisfied could encourage early disclosure of newly created engineered genetic sequences. When the developer of a biotechnology product based on EGC relies on trade secret and patents, there is an incentive to maintain the secrecy of the code, at least until a patent application is filed. But because copyright vests as soon as it is fixed in a tangible medium[159] - which could be in written form or embodied in a DNA molecule - it becomes less necessary to maintain secrecy or to secure confidentiality agreements and contractual restrictions or to file a patent application in order to secure some proprietary position. Again, the CONTU Report specifically identified this as one of the benefits of copyright for computer programs, noting that copyright protection reduces the cost associated with maintaining secrecy, and that it also promotes public dissemination.[160]

C. Limitations on Infringement Liability

A number of the established doctrines pertaining to copyright infringement could be interpreted in a manner that promotes innovation in EGC and synthetic biology in general, while at the same time addresses attendant policy concerns. Again, precedent gleaned from software copyright cases could prove extremely valuable in shaping the contours of infringement liability for EGC.

1. The Requirement of Actual Copying

Infringement of copyright's reproduction right requires proof of actual copying.[161] As a corollary, independent creation of a copyrighted work does not constitute copyright infringement, even if the two works are identical.[162] This fundamental feature of copyright law has important policy implications and should alleviate many of the concerns raised with respect to extension of copyright to DNA. For example, some might question whether copyright on an EGC might inadvertently cover a naturally occurring DNA molecule that happens to share the same sequence. But if someone came up with a synthetic sequence and it turned out that the

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influential Final Report in 1978, which concluded not only that copyright protection for computer programs was justified both in terms of legal doctrine and innovation policy but that computer programs in fact already were copyrightable under both the 1976 and 1909 Copyright Acts. *Id.* at 16-17.

159. 17 U.S.C. § 102(a).

160. *Id.* at 17.

161. Arnstein v. Porter, 154 F.2d 464, 468 (2d Cir. 1946).

162. Calhoun v. Lillenas Publ'g, 298 F.3d 1228, 1232–33 (11th Cir. 2002).

sequence actually already existed in nature, it would not constitute infringement for someone else to subsequently discover the naturally occurring version. Furthermore, anyone seeking to use that DNA sequence could do so without infringing, because they would be copying from the natural sequence rather than from the copyrighted synthetic one, regardless of whether or not the synthetic sequence was copyrighted before the discovery of the natural one.

Copyright is particularly suited to policing against unauthorized literal copying. In the context of software, literal copying typically equates with piracy, i.e., the illicit reproduction of exact copies of a software product. EGC is likewise particularly vulnerable to piracy, especially when it is made widely available to consumers in a self-replicable format, such as a seed.[163] Copyright law's prohibition against literal copying could prove very useful in preventing piracy of engineered DNA products. In the case of a complex piece of EGC, proving literal infringement should be straightforward, and in many instances, copyright would likely be much easier to enforce than patent rights.

There are important limitations, however, even in the context of literal infringement. Literal copying is not infringement, for example, if the copying is limited to the ideas of a work, as discussed below.[164] On the other hand, copyright has a number of advantages over patents in terms of enforceability, such as civil forfeiture provisions,[165] impoundment,[166] criminal sanctions,[167] and provisions for enlisting the aid of the U.S Customs Service in blocking the importation of pirated copies.[168]

2. The Idea-Expression Dichotomy

The protection afforded by copyright does not "extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work."[169] Section 102(b) codifies this longstanding common-law principle known as the "idea-expression

163. *See* Holman, *A Bellwether*, *supra* note 26, at 670.
164. *See infra* Section VI.C.2.
165. 18 U.S.C. § 981 (2012).
166. 17 *id.* § 503.
167. *Id.* § 506; 18 *id.* § 2319.
168. 19 C.F.R. § 133.31 (2016).
169. 17 U.S.C. § 102(b).

dichotomy."[170] The prohibition against copyrighting ideas, methods of operation, and the like has often been invoked as a policy lever to limit the scope of copyright protection with respect to software.[171] Similarly, it could serve as a useful lever to regulate and limit the scope of protection available for engineered DNA.

For example, in *Apple Computer, Inc. v. Franklin Computer Corp.*, the court explained "that in the context before us, a program for an operating system, the line [between idea and expression] must be a pragmatic one, which also keeps in consideration 'the preservation of the balance between competition and protection reflected in the patent and copyright laws.'"[172] The court found that the focus of the issue of copyrightability must be on whether the underlying idea is capable of alternate modes of expression.[173] As applied to operating system software, the court found that "[i]f other programs can be written or created which perform the same function as Apple's operating system program, then that program is an expression of the idea and hence copyrightable."[174] The same rationale should apply to EGC: EGC is copyrightable if, and only if, alternative non-copyrighted EGC can be designed which performs the same function.

When courts first began applying the idea-expression dichotomy to software, they struggled with the incongruity between software and traditionally copyrightable material.[175] Unlike traditional copyrightable subject matter, software tends to be primarily functional, lacking readily identifiable aesthetic elements (at least to a lay observer).[176] Fortunately, the numerous judicial decisions involving copyright protection for software issued over the last four decades provide a useful roadmap as to how to go about incorporating similar limitations with respect to EGC, facilitated by the close analogy between EGC and computer code.[177]

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170. Golan v. Holder, 132 S. Ct. 873, 890 (2012); *see* H.R. REP. NO. 94-1476, at 56 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 5659, 5670.

171. *See infra* Section VI.C.2.

172. 714 F.2d 1240, 1253 (3d Cir. 1983) (quoting Herbert Rosenthal Jewelry Corp. v. Kalpakian, 446 F.2d 738, 742 (9th Cir. 1971)).

173. *Id.*

174. *Id.*

175. *See, e.g.*, Comput. Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 704 (2d Cir. 1992) (citing SAS Inst., Inc. v. S & H Comput. Sys., Inc., 605 F. Supp. 816, 829 (M.D. Tenn. 1985)) ("The essentially utilitarian nature of a computer program further complicates the task of distilling its idea from its expression.").

176. *Id.*

177. *See generally* 4 NIMMER ON COPYRIGHT, *supra* note 59, § 13.03.

The idea-expression dichotomy has been invoked in the context of software as a doctrinal tool for limiting the scope of protection in a manner that does not tie up software function, but instead extends only the particular code used to achieve that function and relatively close variants thereof.[178] This modern manifestation of the dichotomy has resulted in a copyright regime that leaves open the ability of others to engineer computer programs that achieve the same functionality, while still creating a basis for liability in the case of piracy and direct copying. Importantly, although patents have been granted that broadly cover software-implemented algorithms and which are not limited to any specific code used to achieve that implementation, under well-established principles of copyright law, the algorithm itself cannot be copyrighted, only the specific code used to implement it (and in some cases involving non-literal infringement, relatively close variants).[179] Today, the courts routinely invalidate software patent claims of this type, invoking the Supreme Court's decision in *Alice*, and revealing that the scope of protection provided by these patents was largely illusory.[180] Although the protection provided by copyright is substantially narrower, it has been much less controversial and shows no signs of being undercut in the manner that patent protection has been.

The idea-expression dichotomy could be enlisted as a policy lever to limit the scope of protection available for EGC as compared to other copyrighted works. *Feist* suggests that factual works will often receive only relatively "thin protection."[181] Based on this aspect of *Feist*, the Court of Appeals for the Second Circuit has, for example, found only thin protection for maps, essentially limiting the protection to original selection and arrangement of expressive elements.[182] Analogous reasoning could support similarly narrow protection for EGC.

Delineating the boundary between idea and expression is far from an exact science, as aptly noted by Judge Learned Hand:

> Upon any work . . . a great number of patterns of increasing generality will fit equally well, as more and more of the incident is left out. . . . [T]here is a point in this series of abstractions where they are no longer protected, since otherwise the [copyright owner] could prevent the use of his "ideas," to which,

178. *Id.*; *see also Altai*, 982 F.2d at 714.
179. Diamond v. Diehr, 450 U.S. 175, 219-20 (1981).
180. *See* Sachs, *supra* note 48.
181. Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 349 (1991).
182. Streetwise Maps, Inc. v. VanDam, Inc., 159 F.3d 739, 748 (2d Cir. 1998).

> apart from their expression, his property is never extended. Nobody has ever been able to fix that boundary, and nobody ever can.[183]

But it is this very ambiguity that courts have leveraged in applying the idea-expression dichotomy in a manner designed to promote innovation policy in the context of software, and which could likewise be enlisted to meter the scope of protection available to engineered DNA. Depending upon where a court draws the boundary between idea and expression, which as Judge Learned Hand notes is open to considerable judgment and discretion, non-literal copying can constitute either infringing appropriation of expression or non-infringing use of an uncopyrightable idea.

An example of this principle at work arose in the case of *Kregos v. Associated Press*, where judges of a Second Circuit panel came to opposite conclusions on a question of non-literal infringement, based on the level of abstraction at which the idea of the copyrighted work was defined.[184] The copyrighted work was a "baseball pitching form" providing various statistics "concerning the past performances of the opposing pitchers scheduled to start each day's baseball games."[185] The two-judge majority sided with the district court and defined the idea of the work as "to publish in outcome predictive pitching form."[186] Since there are multiple ways of expressing this idea, according to these judges, copyright protection was available for the plaintiff's specific selection of statistics. In contrast, the dissenting judge contended that the plaintiff's idea is that "the nine statistics he has selected are the most significant ones to consider when attempting to predict the outcome of a baseball game. Unquestionably, if that is the idea for purposes of merger analysis, the merger of that idea and its expression has occurred - by definition."[187] This judge would have denied plaintiff any scope of protection. By analogy, the same analysis could be used to justify either thin protection, or no protection at all, for an ECG, depending on the policy leanings of a judge deciding the matter.

a) Merger Doctrine

The merger doctrine is a manifestation of the idea-expression dichotomy that could be applied to meter the scope of copyright protection available

183. Nichols v. Universal Pictures Corp., 45 F.2d 119, 121 (2d Cir. 1930) (internal citations omitted).

184. 937 F.2d 700 (2d Cir. 1991).

185. *Id.* at 702.

186. *Id.* at 706 (citation omitted).

187. *Id.*

for EGC. Under the merger doctrine, if an idea "can only be expressed in a limited number of ways," those means of expression "cannot be protected, lest one author own the idea itself."[188] Under such circumstances, the idea and its expression are considered "merged."[189] For example, if, within a given technological environment, computer code must be drafted in a specific way in order to instruct the computer to carry out a particular function, then the expression "merges" with the function, rendering the code uncopyrightable.

In *Altai*, for example, the court began by describing the line between idea and expression as a pragmatic one, particularly in the case of software, which courts should delineate on the basis of policy.[190] Applying this principle, the court concluded that software features "dictated by considerations of efficiency" are not protectable, since "the more efficient a set of modules are, the more closely they approximate the idea or process embodied in that particular aspect of the program's structure."[191] *Altai* noted that

> [w]hile, hypothetically, there might be a myriad of ways in which a programmer may effectuate certain functions within a program,-- i.e., express the idea embodied in a given subroutine -- efficiency concerns may so narrow the practical range of choice as to make only one or two forms of expression workable options.[192]

On the other hand, the court recognized that "[o]f course, not all program structure is informed by efficiency concerns."[193] Based on these considerations, the court concluded that

> in order to determine whether the merger doctrine precludes copyright protection to an aspect of a program's structure that is so oriented, a court must inquire "whether the use of *this particular set* of modules is necessary efficiently to implement that part of the program's process" being implemented. If the answer is yes, then the expression represented by the

188. Zalewski v. Cicero Builder Dev., Inc., 754 F.3d 95, 102-03 (2d Cir. 2014).
189. *See id.* at 103.
190. Comput. Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 711 (2d Cir. 1992).
191. *Id.* at 707-08.
192. *Id.* at 708.
193. *Id.*

> programmer's choice of a specific module or group of modules has merged with their underlying idea and is unprotected.[194]

Similarly, if there are only a few ways of expressing a given idea, the available scope of protection can be extremely narrow. For example, in a recent case involving a photographer who took photos of a vodka manufacturer's blue vodka bottle and then sued the vodka manufacture for using someone else's photographs in its advertisements, the Court of Appeals for the Ninth Circuit stated that this "litigation is fundamentally about how many ways one can create an advertising photograph . . . of a blue vodka bottle. We conclude there are not very many."[195] Because of the limited number of ways of expressing the idea, the court held that only "virtually identical copy" would be actionable.[196] Similarly, in a case where there are limited ways of achieving the function of a given EGC, that sequence might be afforded extremely narrow scope of protection.

As a corollary, the fact that two software programs both use the same efficient means of accomplishing some function is not necessarily probative of copying.[197]

The Federal Circuit recently addressed merger in the context of software in *Oracle America, Inc. v. Google Inc.*[198] The court began by noting that, as applied to computer programs, the merger doctrine "means that when specific [parts of the code], even though previously copyrighted, are the only and essential means of accomplishing a given task, their later use by another will not amount to infringement."[199] At the same time, the court observed, the "unique arrangement of computer program expression . . . does not merge with the process so long as alternate expressions are available."[200] With respect to the software at issue in the case, merger did not apply because "[t]he evidence showed that Oracle had 'unlimited options as to the selection and arrangement of the 7000 lines Google copied.'"[201] The Federal Circuit pointed out that the district court had

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194. *Id.* (internal citation omitted) (citing Steven R. Englund, Note, *Idea, Process, or Protected Expression?: Determining the Scope of Copyright Protection of the Structure of Computer Programs*, 88 MICH. L. REV. 866, 902-03 (1990)).

195. Ets-Hokin v. Skyy Spirits Inc., 323 F.3d 763, 764 (9th Cir. 2003).

196. *Id.*

197. *Altai*, 982 F.2d at 709.

198. 750 F.3d 1339, 1358-62 (Fed. Cir. 2014).

199. *Id.* at 1360 (alteration in original) (quoting *Altai*, 982 F.2d at 708).

200. *Id.* (omission in original) (quoting Atari Games Corp. v. Nintendo of Am. Inc., 975 F.2d 832, 840 (Fed. Cir. 1992)).

201. *Id.* at 1361 (citation omitted).

"erred in focusing its merger analysis on the options available to Google at the time of copying. It is well established that copyrightability and the scope of protectable activity are to be evaluated at the time of creation, not at the time of infringement."[202]

Many of the policy-driven applications of the merger doctrine to software could be readily extended to EGC. For example, the sequence of a cDNA molecule corresponds exactly to a naturally occurring mRNA from which it is derived, and could be denied copyright protection under the merger doctrine, based on the rationale that there is only one way to express that particular idea. Even if there are many ways of achieving the same outcome, such as encoding a specific protein, if only a very limited number of those alternatives are the most efficient, then under principles of merger those most efficient might be ineligible for copyright protection. This could be the case, for example, when a particular optimized codon sequence is deemed necessary for the most efficient expression of a protein.

b) Scènes-à-faire

As recently observed by the Second Circuit, "the doctrine of '*scènes-à-faire*' teaches that elements of a work that are 'indispensable, or at least standard, in the treatment of a given topic'—like cowboys, bank robbers, and shootouts in stories of the American West—get no protection."[203] In *Altai*, the court applied the *scènes-à-faire* doctrine to deny copyright protection to elements of a computer program "dictated by external factors."[204] The court cited Professor Nimmer for the proposition that "in many instances it is virtually impossible to write a program to perform particular functions in a specific computing environment without employing standard techniques."[205] The court found this to be the

> result of the fact that a programmer's freedom of design choice is often circumscribed by extrinsic considerations such as (1) the mechanical specifications of the computer on which a particular program is intended to run; (2) compatibility requirements of other programs with which a program is designed to operate in conjunction; (3) computer manufacturers' design standards; (4)

202. *Id.*

203. Zalewski v. Cicero Builder Dev., Inc., 754 F.3d 95, 102 (2d Cir. 2014) (emphasis added) (internal citation omitted).

204. Comput. Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 709 (2d Cir. 1992) (emphasis omitted).

205. *Id.* (quoting 3 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.03[F][3], at 13-65 (1991) [hereinafter NIMMER ON COPYRIGHT, 1991 ED.]).

> demands of the industry being serviced; and (5) widely accepted programming practices within the computer industry.[206]

The court concluded that, in assessing the copyright protection of software, the court must "examine the structural content of [the] allegedly [infringing] program for elements that might [be] dictated by external factors."[207] Those elements will not receive copyright protection.[208]

The *Altai* court also found that elements of a computer program taken from the public domain are not protectable, but are instead free for the taking by the general public, regardless of whether it might be included in an otherwise copyrighted work.[209] With respect to software, the court found that this precluded, for example, copyright for program elements that might have "entered the public domain by virtue of freely accessible program exchanges and the like."[210] Generally speaking, some computer routines may be so standard in the programming industry that the *scènes-à-faire* doctrine deprives them of copyright protection.

In *Oracle*, the Federal Circuit noted that "[i]n the computer context, 'the scenes a faire doctrine denies protection to program elements that are dictated by external factors such as "the mechanical specifications of the computer on which a particular program is intended to run" or "widely accepted programming practices within the computer industry."'"[211] The court noted that the *scènes-à-faire* doctrine, like merger, is a component of the infringement analysis, and as such "the expression is not excluded from copyright protection; it is just that certain copying is forgiven as a necessary incident of *any* expression of the underlying idea."[212]

Like merger, the *scenes a faire* doctrine, as it has developed with respect to software, could be readily applied to EGC. Certain genetic elements might be considered so standard that they would be denied copyright protection, even if incorporated into an otherwise copyrightable genetic sequence. Furthermore, genetic elements and motifs dictated by external

206. *Id.* at 709-10 (citing NIMMER ON COPYRIGHT, 1991 ED., *supra* note 205, at 13-66-71).
207. *Id.* at 710.
208. *Id.*
209. *Id.*
210. *Id.*
211. Oracle Am., Inc. v. Google Inc., 750 F.3d 1339, 1363 (Fed. Cir. 2014) (emphasis added) (quoting Softel, Inc. v. Dragon Med. & Sci. Commc'ns Inc., 118 F.3d, 955 (2d Cir. 1997)).
212. *Id.* at 1364 (citing Satava v. Lowery, 323 F.3d 805, 810 n.3 (9th Cir. 2003) ("The Ninth Circuit treats scenes a faire as a defense to infringement rather than as a barrier to copyrightability.")).

considerations, derived from the public domain, or routinely found in EGC could likewise be excluded from copyright under a policy-driven interpretation of the *scenes a faire* doctrine.

3. Non-Literal Copyright Infringement

It is well established that copyright extends not only to the literal aspects (i.e., the actual text) of an original literary work, but also to its non-literal aspects, such as the plot of a novel - at least to the extent those non-literal aspects are original.[213] As Judge Learned Hand observed, "[i]t is of course essential to any protection of literary property . . . that the right cannot be limited literally to the text, else a plagiarist would escape by immaterial variations."[214] "Thus, where 'the fundamental essence or structure of one work is duplicated in another,' courts have found copyright infringement."[215] In *Altai*, the Second Circuit reasoned that "if the non-literal structures of literary works are protected by copyright; and if computer programs are literary works, as we are told by the legislature; then the non-literal structures of computer programs are protected by copyright."[216] Similarly, in *Oracle*, the Federal Circuit endorsed Ninth Circuit case law recognizing that the structure, sequence, and organization of a computer program is eligible for copyright protection where it qualifies as an expression of an idea, rather than the idea itself.[217]

Just as the *Altai* court relied on analogy to other literary works, the analogy between engineered DNA and software supports the idea that non-literal protection should be available for EGC. But as noted in *Altai*, the recognition of the existence of non-literal protection does not end that analysis. The court must still "determine the scope of copyright protection that extends to a computer program's non-literal structure," and, thus, courts can use this doctrine as a policy lever to adjust the scope of protection for EGC.[218]

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213. *See, e.g.*, Twin Peaks Prods., Inc. v. Publ'ns Int'l, Ltd., 996 F.2d 1366, 1372-73 (2d Cir. 1993).

214. Nichols v. Universal Pictures Corp., 45 F.2d 119, 121 (2d Cir. 1930).

215. Comput. Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 701 (2d Cir. 1992) (quoting 4 NIMMER ON COPYRIGHT, 1991 ED., *supra* note 205, § 13.03 [A][1]).

216. *Id.* at 702 (internal citation omitted) (citing Whelan Assocs. v. Jaslow Dental Lab., Inc., 797 F.2d 1222, 1234 (3d Cir. 1986) ("By analogy to other literary works, it would appear that the copyrights of computer programs can be infringed even absent copying of the literal elements of the program.")).

217. *Oracle*, 750 F.3d at 1366 (citing Johnson Controls, Inc. v. Phoenix Control Sys., Inc., 886 F.2d 1173, 1175 (9th Cir. 1989)).

218. *Altai*, 982 F.2d at 703.

Altai emphasized that, in distinguishing idea from expression, the court should emphasize "practical considerations" rather than relying "too heavily on metaphysical distinctions."[219] The court based this policy on the functional characteristics of computer programs as compared to other more traditional copyrightable works.[220] This focus on practical considerations should also apply to EGC.

Another important characteristic shared by software and EGC is that both typically embody a modular structure and, as such, are readily susceptible to representation at different levels of abstraction.[221] At a low level of abstraction, software is, of course, described by its code. All but the most simple computer programs, however, comprise structured arrangements of modules, e.g., subroutines and parameter lists, which are better represented by a more abstract organizational structure or flowchart.[222] The modules can themselves often be broken down into more basic subroutines and other more fundamental elements, a description of which would result in a somewhat less abstract representation of the software, somewhere between a high level flow chart and literal code.[223] The modular nature of software facilitates the design of complex software programs, since an engineer working at a higher level of abstraction can focus on the selection and arrangement of modules without concerning herself with the specific code underlying those modules.[224] The modular nature of software has led courts to conceptualize software at varying levels of abstraction and to establish that non-literal copyright infringement can exist in cases where the structure of module arrangements has been copied, even in the absence of literal copying of the code.[225]

As described in a previous article, synthetic biologists are increasingly conceptualizing engineered genetic sequences at different levels of abstraction and taking advantage of the modular nature of genes and genetic control elements to facilitate design of increasingly complex synthetic DNA sequences.[226] Not only does the complexity and modular nature of the information content of engineered genetic sequences support an extension of copyright to protect them, it also suggests that protection against non-

219. *Id.* at 706.
220. *Id.*
221. Holman, *Developments*, *supra* note 2, at 424.
222. *Altai*, 982 F.2d at 697-98.
223. *Id.*
224. *Id.*
225. *Id.* at 702.
226. Holman, *Developments*, *supra* note 2, at 424.

literal copying of higher-order structures might be appropriate. Software copyright cases could provide useful precedent for cases involving these more complex EGCs where the court applied an abstraction test like those described below and where the court considered issues of non-literal copying.

The standard test for non-literal infringement centers around a search for "substantial similarity."[227] In order to determine whether an allegedly infringing work is substantially similar to a copyrighted work, courts have traditionally applied an "ordinary observer" test.[228] However, in *Whelan Associates v. Jaslow Dental Laboratory*, the Court of Appeals for the Third Circuit found the ordinary observer test unsuited for assessing substantial similarity in the context of copyrighted computer software.[229] In view of the complexity of computer software and the general public's unfamiliarity with the subject, the court held that it made little sense to expect an ordinary juror to make the determination.[230] Instead, the proper audience for assessing substantial similarity of computer programs is one skilled in the technology of computer programming.[231] For the same reason, an assessment of substantial similarity of engineered genetic sequences should be made by one skilled in molecular biology.

Oracle illustrates the potential for relatively broad non-literal protection of computer code. In *Oracle*, the court applied fundamental principles of copyright law to assess infringement, such as evaluating the originality and creativity of the software and considering whether there were alternative ways to implement similar functions, ultimately concluding that Google had non-literally infringed Oracle's copyright in its software.[232] The court repeatedly rejected Google's arguments premised on the alleged functional and utilitarian nature of Oracle's software.[233] The court also rejected

227. *Altai*, 982 F.2d at 706.

228. *Id.* at 713 (citing Arnstein v. Porter, 154 F.2d 464, 473 (2d Cir. 1946)).

229. 797 F.2d 1222, 1233 (3d Cir. 1986).

230. *Id.* at 1247.

231. *Id.* at 1232.

232. Oracle Am., Inc. v. Google Inc., 750 F.3d 1339, 1368 (Fed. Cir. 2014) ("[T]he SSO is original and creative, and . . . could have been written and organized in any number of ways and still have achieved the same functions.").

233. *Id.* at 1379-80 ("Many of Google's arguments, and those of some amici, appear premised on the belief that copyright is not the correct legal ground upon which to protect intellectual property rights to software programs; they opine that patent protection for such programs, with its insistence on non-obviousness, and shorter terms of protection, might be more applicable, and sufficient.").

Google's assertion that there should be no overlap between the scope of protection conferred by patent and copyright.[234]

In *Oracle*, the Federal Circuit applied the "abstraction-filtration-comparison" test in assessing whether the non-literal elements of Oracle's computer program constituted protectable expression, noting that the test addresses the utilitarian nature of computer programs.[235] The court noted that this test was formulated by the Second Circuit, endorsed by the Ninth Circuit, and has been expressly adopted by several other circuits.[236] In applying the abstraction-filtration-comparison test, the court analyzes the work at different levels of abstraction and then filters out unprotectable elements, even if those elements are expressive.[237] If the court determines that any expression, at any level of abstraction, "is dictated by considerations of efficiency, required by factors already external to the program itself, or taken from the public domain," that expression is to be treated as unprotectable and not considered in the assessment for non-literal similarity.[238] A modified version of this test could likewise be fashioned for EGC to achieve a scope of non-literal protection appropriate from the perspective of innovation policy.

4. De minimis *Copying*

The judge-made doctrine of *de minimis* copying might also shield some forms of benign, or even socially useful, copying of EGC from infringement liability. In *Davis v. The Gap, Inc.*, the Second Circuit provided the following explanation of the *de minimis* doctrine, as well as its policy underpinning:

> Trivial copying is a significant part of modern life. Most honest citizens in the modern world frequently engage, without hesitation, in trivial copying that, but for the *de minimis* doctrine, would technically constitute a violation of law. We do not hesitate to make a photocopy of a letter from a friend to show another friend, or other favorite cartoon to post on the

234. *Id.* at 1380 (quoting Mazer v. Stein, 347 U.S. 201, 217 (1954)) ("Importantly for our purposes, the Supreme Court has made clear that '[n]either the Copyright Statute nor any other says that because a thing is patentable it may not be copyrighted.'").

235. *Id.* at 1358.

236. *Id.* at 1357 (citing Sega Enters. Ltd. v. Accolade, Inc., 977 F.2d 1510, 1525 (9th Cir.1992) ("In our view, in light of the essentially utilitarian nature of computer programs, the Second Circuit's approach is an appropriate one.").

237. *Id.* at 1357-58.

238. *Id.*

> refrigerator. Parents in Central Park photograph their children perched on Josè de Creeft's Alice in Wonderland sculpture. We record television programs aired while we are out, so as to watch them at a more convenient hour. Waiters at a restaurant sing "Happy Birthday" at a patron's table. When we do such things, it is not that we are breaking the law but unlikely to be sued given the high cost of litigation. Because of the *de minimis* doctrine, in trivial instances of copying, we are in fact not breaking the law.[239]

Application of this doctrine might particularly be useful in shielding DIY synthetic biologists and other non-commercial actors from liability. There is an overlap between the de minimis defense and fair use, a critically important aspect of copyright law to which I will now turn.

5. Fair Use

The doctrine of fair use originated in the courts and was codified by Congress in 1976.[240] In essence, it permits certain otherwise infringing uses of a copyrighted work when enforcing a copyright would "stifle the very creativity which [copyright] law is designed to foster."[241] Fair use helps to resolve "the inherent tension in the need simultaneously to protect copyrighted material and to allow others to build upon it."[242] It has been characterized as an "equitable rule of reason."[243]

Fair use could play an important role in facilitating certain socially desirable uses of copyrighted EGC. For example, courts have held that "where there is good reason for studying or examining the unprotected aspects of a computer program, disassembly for purposes of such study or examination constitutes fair use."[244] Thus, it is often possible for a competitor to deconstruct a copyrighted computer program to understand its functionality and then use that knowledge to write software that achieves the same functionality by means of different code without incurring liability

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239. Davis v. The Gap, Inc., 246 F.3d 152, 173 (2d Cir. 2001) (footnote omitted); *cf.* Tim Wu, *Tolerated Use*, 31 COLUM J.L. & ARTS. 617 (2008).

240. 17 U.S.C. § 107 (2012); Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 576 (1994).

241. *Campbell*, 510 U.S. at 577 (quoting Stewart v. Abend, 495 U.S. 207, 236 (1990)).

242. *Id.* at 575 (citation omitted).

243. Harper & Row Publishers, Inc. v. Nation Enters., 471 U.S. 539, 550 n.3 (1985) (citations omitted) (quoting Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 448 (1984)).

244. Sega Enters. v. Accolade, 977 F.2d 1510, 1520 (9th Cir. 1993).

for infringement. Copying of protected elements within copyrighted software is permissible fair use if such copying is reasonably necessary in order to access unprotected elements.[245]

In *Sega Enterprises Ltd. v. Accolade, Inc*., for example, the Ninth Circuit found that copying of Sega's software in the course of disassembling the object code embedded in the game software would ordinarily constitute infringement, but in this case was fair use.[246] "[W]here disassembly is the only way to gain access to ideas and functional elements embodied in a copyrighted computer program and where there is a legitimate reason for seeking such access, disassembly is a fair use of the copyrighted work, as a matter of law."[247] Similarly, in *Atari Games Corp. v. Nintendo Inc*., the Federal Circuit, applying Ninth Circuit controlling law, said that Atari could make fair use of the Nintendo program to derive unprotected ideas and processes.[248] The court also indicated that Atari could incorporate into its games aspects of the Nintendo program necessary to unlock the Nintendo console.[249]

Applying the same principle to copyrighted EGC, one should be allowed to copy and manipulate engineered DNA sequences in order to understand unprotected aspects, such as functional attributes of the engineered sequence, without obtaining authorization from the copyright owner. This contrasts with patent law, with respect to which there is no fair use doctrine, and only a minimal (at best) experimental use exception.[250]

Fair use is also enlisted as a doctrinal tool to address interoperability and lock-in concerns.[251] For example, in *Atari*, the court indicated that Atari could incorporate into its games various aspects of the Nintendo program necessary to unlock the Nintendo console.[252] With respect to EGC, fair use could be invoked in a similar manner as a means for addressing analogous concerns.

A work's publication status can be a significant consideration in the fair use analysis: in general, unpublished works are afforded more protection

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245. *Id.*

246. *Id.*

247. *Id.* at 1527-28.

248. Atari Games Corp. v. Nintendo of Am., Inc., 975 F.2d 832, 844 (Fed. Cir. 1992).

249. *Id.*; *see also* Sony Comput. Entm't, Inc. v. Connectix Corp., 203 F.3d 596 (9th Cir. 2000).

250. Madey v. Duke Univ., 307 F.3d 1351, 1258 (Fed. Cir. 2002).

251. *See* Lexmark Int'l, Inc. v. Static Control Components, Inc., 387 F.3d 522, 544-45 (6th Cir. 2004); *Sony Comput.*, 203 F.3d at 602-05; *Sega*, 977 F.2d at 1523-24.

252. *Atari*, 975 F.2d at 844; *see also Sony Comput.*, 203 F.3d at 596.

than published works.[253] The contours of what constitutes "publication" with respect to EGC would no doubt need to be worked out by the courts, but there could be some policy benefit to providing heightened protection for EGC in cases in which the creator seeks to limit disclosure, relative to a situation where the copyright owner more purposefully disseminates the DNA sequence information.

One of the ideas suggested by the CPP group is for the Copyright Office to "provide fair use 'opinion letters.'"[254] CPP has also suggested that market failures, which render it difficult to obtain clearance, should be considered a factor in fair use.[255] These suggestions could find particular applicability in the context of EGC.

6. Inadvertent Infringement

The potential for inadvertent infringement of EGC-based patents has been much discussed, and similar concerns would no doubt arise with respect to copyright on EGC, given that copyright infringement has often been characterized as a matter of strict liability.[256] Particularly when dictated by considerations of policy, however, courts have required a showing of at least some element of volition or causation for a finding of infringement.[257] For example, in *Religious Technology Center v. Netcom On-Line Communication Services, Inc.*, the district court refused to impose direct liability on an Internet service provider, reasoning that "[a]lthough copyright is a strict liability statute, there should still be some element of volition or causation which is lacking where a defendant system is merely used to create a copy by a third party."[258] The Court of Appeals for the Fourth Circuit has endorsed *Netcom*, noting that

> to establish direct liability under . . . the Act, something more must be shown that mere ownership of a machine used by others

253. Harper & Row, Publishers, Inc. v. Nation Enters., 471 U.S. 539, 553 (1985) ("The Senate Report confirms that Congress intended the unpublished nature of the work to figure prominently in fair use analysis.").

254. Samuelson et al., *supra* note 119, at 1206.

255. *Id.* at 1226.

256. Patrick R. Goold, *Is Copyright Infringement a Strict Liability Tort?*, 30 BERKELEY TECH. L.J. 305, 312 (2015).

257. Am. Broad. Cos. v. Aereo, Inc., 134 S. Ct. 2498, 2512 (2014) (Scalia, J., dissenting) ("'The Networks' claim is governed by a simple but profoundly important rule: A defendant may be held directly liable only if it has engaged in volitional conduct that violates the Act.").

258. 907 F. Supp. 1361, 1370 (N.D. Cal. 1995).

> to make illegal copies. There must be actual infringing conduct with a nexus sufficiently close and causal to the illegal copying that one could conclude that the machine owner himself trespassed on the exclusive domain of the copyright owner.[259]

In *Cartoon Network LP v. CSC Holdings, Inc.*, the Second Circuit recently cited *CoStar Group* with approval, "reject[ing] the contention that 'the *Netcom* decision was driven by expedience and that its holding is inconsistent with the established law of copyright,' and [finding *Netcom*] 'a particularly rational interpretation of § 106,' rather than a special-purpose rule applicable only to ISPs."[260] The Second Circuit found that the district court improperly "pigeon-holed the conclusions reached in *Netcom* and its progeny as 'premised on the unique attributes of the Internet.'"[261] To the contrary, the Second Circuit held that

> [w]hile the *Netcom* court was plainly concerned with a theory of direct liability that would effectively 'hold the entire Internet liable' for the conduct of a single user, its reasoning and conclusions, consistent with the precedents of this court and the Supreme Court, and with the text of the Copyright Act, transcend the Internet.[262]

The court further held that "[w]hen there is a dispute as to the author of an allegedly infringing instance of reproduction, *Netcom* and its progeny direct our attention to the volitional conduct that causes the copy to be made."[263]

The rationale underlying these decisions apply in the context of EGC to shield parties from accusations of direct copyright infringement in the absence of sufficient evidence of volitional conduct. For example, a farmer's field could be analogized to the "machine" mentioned in *CoStar Group*, and by analogy, mere ownership of the farmland is not sufficient to create liability if copyrighted seeds are found growing in the field without authorization. Instead, in order to prevail, a copyright owner would be required to prove some volitional conduct "with a nexus sufficiently close and causal to the illegal copying."[264]

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259. CoStar Grp., Inc. v. Loopnet, Inc., 373 F.3d 544, 550 (4th Cir. 2004).

260. 536 F.3d 121, 131 (2d Cir. 2008) (quoting *CoStar Grp.*, 373 F.3d at 549, 551).

261. *Id.* (quoting Twentieth Century Fox Film Corp. v. Cablevision Sys. Corp., 478 F. Supp. 2d 607, 620 (S.D.N.Y. 2007)).

262. *Id.* (internal citations omitted).

263. *Id.*

264. *CoStar Grp.*, 373 F.3d at 550.

Congress might also consider creating statutory safe-harbor provisions to protect certain entities that, as a practical matter, would find it difficult, if not impossible, to avoid unintentionally indirectly infringing copyright in EGC. The Digital Millennium Copyright Act ("DMCA") created safe harbors for Internet service providers ("ISPs"),[265] and similar rights could be appropriate for entities such as DNA synthesis companies like ATUM, firms such as Biobricks Foundation that provide modular EGCs to synthetic biologists,[266] or perhaps even research institutions that work with large numbers of engineered sequences. With respect to engineered seeds and agriculture, safe harbors could be made available to grain elevator operators, seed banks, and other "gatekeepers."

Just as the DMCA requires ISPs to take a number of positive steps towards avoiding infringement in order to qualify for the safeguard and provides that ISPs must comply with "standard technical measures" employed by rights owners to identify and block infringement,[267] there should be a requirement that, in order to benefit from an EGC-specific safe harbor, a firm must adopt and cooperate with technical measures designed to detect and counter infringement. The CPP has noted that since the enactment of the DMCA

> technologies have become much better at recognizing and filtering out infringing copies of works available on or being distributed via the Internet[, and most] of this technology has been developed by small entrepreneurs who see a potential market for the technology among service providers and content companies. The technology is increasingly "smart," that is, capable of determining, for example, how much of a copyrighted movie is contained in a given online file and even whether the file combines video or audio tracks from the movie with new material.[268]

In a similar manner, the creation of a DMCA-like safe harbor regime for EGC copyright could incentivize the development of technologies that could be used to quickly and efficiently identify copyrighted EGC. This would leverage the ability of firms such as these to serve as "gatekeepers,"

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265. 17 U.S.C. § 512 (2012); *see, e.g.*, Viacom Int'l, Inc. v. YouTube, Inc., 676 F.3d 19, 26-28 (2d Cir. 2012).

266. *See The BioBrick® Public Agreement (BPA)*, BIOBRICKS FOUND., https://biobricks.org/bpa/ (last visited May 12, 2017).

267. 17 U.S.C. § 512(i); *Viacom*, 676 F.3d at 27.

268. Samuelson et al., *supra* note 119, at 1217.

with the benefit of shifting enforcement activities away from individual users of EGC.[269]

D. Subject Matter-Specific Statutory Limitations, Exemptions, and Compulsory Licenses

Although there are a few subject matter-specific exceptions or limitations in patent law and none relating specifically to ECG, they are quite common in the Copyright Statute. For example, section 106(4) omits sound recordings from the list of works whose copyright holders have a general right of public performance;[270] sections 114 and 115 provide compulsory licenses for certain uses of sound recordings;[271] sections 111 and 118 create compulsory licenses for secondary transmissions of broadcast programming by cable systems and for public broadcasting, respectively;[272] section 117 provides exemptions from liability for certain otherwise-infringing uses of copyrighted software;[273] and section 104 creates exemptions for various acts of technical infringement involving teaching, private homes, and public performance without commercial advantage.[274]

In a similar manner, Congress could create subject matter-specific limitations with respect to the availability and/or enforceability of copyright on EGC. For example, exemptions could be crafted for certain socially desirable activities, such as teaching or noncommercial use. Compulsory licensing could be considered as a means for addressing concerns about transaction costs or collective-action concerns and would likely incentivize more efficient private-sector solutions analogous to BMI, ASCAP, and the Copyright Clearance Center.[275] The fact that there is much greater precedent for such alternatives in copyright compared to the patent statute

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269. *Id.*

270. 17 U.S.C. § 106(4).

271. *Id.* §§ 114-15. The Section 115 Reform Act of 2006, H.R.5553, 109th Cong., would have created a blanket license for digital music providers in order to provide legitimate digital music services with an efficient way "to clear all the rights they need to make large numbers of musical works quickly available by an ever-evolving number of digital means while ensuring that the copyright holders are fairly compensated." *Discussion Draft of the Section 115 Reform Act (SIRA) of 2006: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 109th Cong. 58 (2006) (statement of the U.S. Copyright Office).

272. 17 U.S.C. §§ 111, 118.

273. *Id.* § 117.

274. *Id.* § 104. *See generally* BRIAN T. YEH, CONG. RESEARCH SERV., RL33631, COPYRIGHT LICENSING IN MUSIC DISTRIBUTION, REPRODUCTION, AND PUBLIC PERFORMANCE (2015).

275. Samuelson et al., *supra* note 119, at 1202.

could be seen as an advantage of enlisting copyright as an alternative form of protection for EGC.

For example, consider 17 U.S.C. § 114(b), which provides that

> [the] exclusive right of the owner of copyright in a sound recording under clause (1) of section 106 is limited to the right to duplicate . . . . The exclusive right of the owner of a copyright in a sound recording under clause (2) of section 106 is limited to the right to prepare a derivative work in which the actual sounds fixed in the sound recording are . . . altered in sequence or quality. The exclusive rights of the [copyright] owner [under either clause] do not extend to the making or duplication of another sound recording that consists entirely of an independent fixation of other sounds, even though such sounds imitate or simulate those in the copyrighted sound recording.[276]

As explained by *Patry on Copyright*:

> As a result [of 114(b)], where a sound recording is re-recorded using either the same or different musicians, no infringement of the sound recording results since the actual sounds of the original are not duplicated. This is also the case where some, but not all, of the original musicians who performed on the first sound recording are replaced on the new sound recording, and the replacement musicians copy as closely as possible (or in the case of the derivative right, adapt) the original musician's performance.[277]

One could imagine analogous restrictions on EGC copyright, which would limit infringement to copies of DNA whose origin can be traced directly back to the copyrighted EGC. Significantly, this would limit infringement to someone who directly produces copies of copyrighted EGC, such as a farmer who saves and replants seeds bearing copyrighted DNA. On the other hand, it would provide an exemption from liability for someone who actually goes to the trouble of synthesizing the DNA *de novo*, even if that individual had access to the copyrighted sequence and sought to emulate it, or even to reproduce it identically. Although this approach might result in copyright for EGC that is too easy to circumvent, thus providing an inadequate incentive for innovators, it does illustrate the fact that Congress

276. 17 U.S.C. § 114(b).

277. 4 WILLIAM F. PATRY, PATRY ON COPYRIGHT § 12:27, Westlaw (database updated Sept. 2016).

has at its disposal a variety of methods for limiting the scope of copyright protection for EGC if it decides that doing so would further good public policy.

E. Remedies

Remedies could be another lever for addressing some of the policy concerns that have been expressed regarding the potential for copyright on EGC to adversely affect follow-on innovation. Particularly since *eBay Inc. v. MercExchange, L.L.C.*, the courts have recognized that, once liability is found, an injunction is not always the appropriate remedy.[278] In cases where a copyrighted EGC is incorporated into a larger genetic work, for example, the appropriate remedy might be some sort of reasonable royalty that permits continued use of the copyrighted work.[279] The CPP found that "[a]lternative relief may also be appropriate in cases where there is a collective action problem or a market failure due to high transaction costs which leads to a difficulty in clearing all of the rights necessary from a multitude of copyright owners."[280]

F. Open-Source Licensing

In the context of software, open source is well established, and best practices are already in place.[281] Many of these practices, along with experiential knowledge that has been generated in connection with the open-source movement, could be adapted for use in the context of biotechnology and EGC. In addition, the courts are developing a body of case law that provides guidance as to how to effectively use copyright to promote open source. In *Jacobsen v. Katzer*, for example, the Federal Circuit upheld the enforceability of an open-source copyright license,[282] a move seen by many as validating and supporting the open-source movement, at least in the context of copyright.[283] While this precedent is arising primarily in the context of software, it should facilitate accelerated adoption of open source as a viable alternative for biotechnology. Patents,

278. 547 U.S. 388, 390 (2006).

279. *Id.* at 392-93.

280. Samuelson et al., *supra* note 119, at 1226.

281. Greg DeKoenigsberg & Michael DeHaan, *Community at the Speed of Light: Best Practices for the New Era of Open Source*, OPENSOURCE.COM (Sept. 2014), https://opensource.com/business/14/9/community-best-practices-new-era-open-source.

282. 535 F.3d 1373, 1382-83 (Fed. Cir. 2008).

283. *See generally* Jennifer Buchanan O'Neill & Christopher J. Gaspar, *What Can Decisions by European Courts Teach Us About the Future of Open-Source Litigation in the United States*, 38 AIPLA Q.J. 437 (2010).

on the other hand, seem less suited to serve as the foundation for a well-functioning, open-source biotechnology movement.[284]

VII. Conclusion

Although extending copyright to EGC would raise plausible policy concerns, it should be possible to effectively ameliorate them by interpreting, and if necessary limiting, copyright law in a manner that promotes innovation. This has often been the case in the past when copyright law has extended to new subject matter, such as sound recordings, which are afforded much narrower rights than other copyrightable materials, and software, which has also been limited for technology-specific policy reasons. The potential positive benefits of extending copyright to EGC should be seriously considered, and if they are found substantial, as I believe they are, it only makes sense to move toward a copyright regime that accommodates genetic sequences, including any necessary safeguards and restrictions, rather than holding to the current status quo that denies them copyright protection altogether.

284. Sara Boettiger & Dan L. Burk, *Open Source Patenting*, 1 J. INT'L BIOTECHNOLOGY LAW 221 (2004).