

# PROTECTING OUR GENETIC CODE: CAN COPYRIGHT SUCCEED WHERE PATENTS HAVE FAILED?

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## INTRODUCTION

When it comes to genetic innovation, what is the proper balance between rewarding an inventor's innovative efforts and facilitating public access to information? Some legal scholars argue that public policy favors free access to information, particularly in regard to potentially life-altering discoveries.<sup>1</sup> Others emphasize the need for rewarding the significant investment of time, effort, and resources that inventors put into bringing such discoveries into existence.<sup>2</sup> Despite several recent judicial decisions touching on the matter, a clear consensus has yet to emerge.<sup>3</sup> This Note is an attempt to resolve this issue.

In 2013, the Supreme Court faced this policy-balancing issue in *Association for Molecular Pathology v. Myriad Genetics*.<sup>4</sup> After a significant research investment, Myriad Genetics, Inc. (Myriad), had discovered the sequences of two breast cancer marker genes,<sup>5</sup> a mutation in either of which drastically increases the risk of developing breast cancer.<sup>6</sup> For each gene, Myriad obtained patents for the entire naturally occurring genomic DNA (gDNA) sequences, as well as smaller man-made copies, called complementary DNA (cDNA).<sup>7</sup> Myriad had sole control over any isolation

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1. See Fazal Khan & Lindsay Kessler, *Genomics Unbound: The Scientific and Legal Case Against Patents Based on Naturally Occurring DNA Sequences*, 13 NEV. L.J. 668, 680-84 (2013).

2. See Christopher M. Holman, *Copyright for Engineered DNA: An Idea Whose Time Has Come?*, 113 W. VA. L. REV. 699, 707 (2011).

3. See generally Christopher M. Holman, *Developments in Synthetic Biology Are Altering the IP Imperatives of Biotechnology*, 17 VAND. J. ENT. & TECH. L. 385 (2015).

4. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 585-86 (2013).

5. Myriad was the first to determine the location and sequence of the BRCA1 and BRCA2 genes, hailed by many as a valuable medical breakthrough. *Id.* at 2112.

6. While the average woman has a 12-13% risk of breast cancer, the rate increases to 50-80% for women carrying certain genetic mutations. *Id.*

7. *Id.* at 583-85.

or use of a fragment from either sequence, no matter the intended purpose,<sup>8</sup> which allowed it to carve-out the entire market of breast cancer genetic testing for itself.<sup>9</sup>

In response, a diverse group of patients, researchers, genetic counselors, and medical organizations brought suit against Myriad and the Patent and Trademark Office (PTO), seeking to invalidate the patents.<sup>10</sup> After the case worked its way up through the federal court system, the Supreme Court was confronted with the question of whether to uphold genetic sequence patents, and to what extent.<sup>11</sup> The level of controversy was apparent, with over 100 amicus briefs submitted to the Court by special interest groups from all sides of the debate.<sup>12</sup> The Court ultimately reached the conclusion that “naturally occurring” genomic DNA (gDNA) sequences were not worthy of patent protection, prohibiting gene patents moving forward.<sup>13</sup> However, the Court came to the confusing conclusion that patents for identical “man-made” complimentary DNA (cDNA) sequences were valid.<sup>14</sup> Thus, prospective patentees could work around the gene patent prohibition by simply translating their gDNA sequences into cDNA. This illogical precedent, by which all subsequent cases have been judged, only serves to exacerbate the policy concerns at issue with genetic innovation.<sup>15</sup>

Since the traditional patent system has favored awarding genetic monopolies over promoting the progress of science, it may be time to welcome the expansion of copyright protection into the evolving field of

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8. *Id.* at 585. The human body is primarily composed of proteins, which are essential to performing all of the functions necessary for survival. *What Are Proteins and What Do They Do?*, NAT'L INST. OF HEALTH: U.S. NAT'L LIBR. MED.: GENETICS HOME REF. (Feb. 19, 2019), <https://ghr.nlm.nih.gov/primer/howgeneswork/protein>. DNA, or deoxyribonucleic acid, serves as the blueprint for building all proteins. *See Myriad*, 569 U.S. at 581. In order to be useful, DNA must first be translated into RNA, or ribonucleic acid and non-coding regions of the sequence removed. Khan & Kessler, *supra* note 1, at 678. Once the RNA is processed, the cell's genetic machinery uses the information to produce sufficient copies of the desired protein. *See Myriad*, 569 U.S. at 581-82. Since RNA molecules are temporary and unstable, genetic researchers exploit this natural process by artificially translating processed RNA sequences back into DNA, creating stable cDNA sequences that can be manipulated in the lab. Khan & Kessler, *supra* note 1, at 678. Since virtually all genetic research takes advantage of this natural process, Myriad's BRCA1 and BRCA2 gene patents, consisting of nearly 100 million nucleotides each, prevented the use of any strand of 15 or more nucleotides within the parent sequences. *See Myriad*, 569 U.S. at 585.

9. *Myriad*, 569 U.S. at 585-86.

10. *Id.* at 586.

11. *See id.* at 585-89.

12. *Id.*

13. *Id.* at 580.

14. *Id.*

15. *See Khan & Kessler, supra* note 1, at 680-86 (noting that gene patents lock down innovation, limit access to diagnostic testing, diminish the quality of genetic testing available, and cause disputes between insurance carriers and consumers).

genetics.<sup>16</sup> Patents remain essential for the protection of new methods and processes (such as medical tests and treatments), but have proven ineffective at protecting the genetic sequences that result from innovative biomedical research.<sup>17</sup> In terms of intellectual property, genetic sequences are virtually indistinguishable from computer code,<sup>18</sup> which has long been afforded dual patent/copyright protection.<sup>19</sup> Just as computer code embodies a set of instructions to be used in a machine, genetic code similarly embodies a set of instructions to be used by a living, biological “machine.”<sup>20</sup> When such sequences satisfy all other requirements of copyright law, there is no reason for registration to be refused.

Genetic Copyrights would more properly balance public and private interests in gene sequencing, but custom and practice has so far prevented consideration of protection outside of the current Patent system. This note begins in Part I by analyzing the origin and effects of the current gene patent system, which heavily favors inventors. This system is detrimental to the public interest, limiting innovation, competition, and patient access. Part II of this note examines how custom and practice has prevented the evolution of proper protection for genetic sequences. Specifically, that the current gene patent system was heavily shaped by concerns to avoid disruption in the biomedical industry. In addition, genetic copyrights have thus far been denied, simply due to the sequences’ perceived patentability. However, despite such misplaced resistance, gene sequences are copyrightable and should be recognized as such.

In Part III, this paper will explore how a genetic copyright system would more properly balance the interests of private inventors with those of the public. A copyright system would better serve the public by promoting access to, and use of, genetic information. Further, copyright protection would better serve inventors, by allowing them to focus on innovation, rather

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

17. See Holman, *supra* note 3, at 443-44 (noting a trend toward weaker protection for biotechnology).

18. According to Holman:

[T]he analogy between software code and genetic code is striking. A genetic sequence provides a series of instructions directing a living [machine] to perform functions dictated by the instructions. Genetic engineering permits a human to dictate these instructions. Like a computer program, a genetic sequence can [also] be expressed in a format directly interpretable by a human . . .

Holman, *supra* note 2, at 711-13.

19. *Id.* at 709-11 (noting that software received Copyright protection in 1980, though software innovation had really begun in the 1960s and 70s).

20. See Irving Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 191, 203 (1982).

than exploitation. This note concludes that a genetic copyright system is essential to promote the progress of science and reach a proper balance between public and private interests in genetic sequences.

#### I. THE CURRENT GENE PATENT SYSTEM

According to the American Civil Liberties Union (ACLU), which orchestrated much of the Myriad opposition, the patenting of human genes creates a constitutional issue:

[G]ene patents undermine the free exchange of information and scientific freedom, bodily integrity, and women's health. In granting exclusive rights to gene patent holders, the U.S. government in essence gives those patent holders complete control over those genes and the information contained within them. This interferes with a person's right to know about his or her own genetic makeup and scientists' rights to study the human genome and develop new genetic tests. Granting a monopoly on fundamental pieces of knowledge infringes on First Amendment rights, which protect the freedom of scientific inquiry and the free exchange of knowledge and ideas.<sup>21</sup>

The Supreme Court's decision in *Myriad*, however, did little to alleviate the constitutional tensions surrounding the patentability of genetic sequence-based innovation.

##### A. *Patents are Meant "to Promote the Progress of Science"*

The Patent Clause, Article I, Section 8 of the Constitution, grants Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . ."<sup>22</sup> In considering this provision, many of the Framers expressed concerns over the creation of state-granted monopolies,<sup>23</sup> a problem the British Courts had disposed of 150 years prior in the Statute of Monopolies.<sup>24</sup> After Thomas Jefferson voiced concern over the lack of an express "restriction against monopolies," James Madison replied that:

With regard to Monopolies they are justly classed among the greatest nuisances in Government. But it is clear that as encouragements to . . . ingenious discoveries, they are not too valuable to be wholly renounced?

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21. ACLU, LEGAL CHALLENGE TO HUMAN GENE PATENTS: BRCA GENES AND PATENTS – FAQ 5 (2009), [https://www.aclu.org/files/pdfs/freespeech/brca\\_qanda.pdf](https://www.aclu.org/files/pdfs/freespeech/brca_qanda.pdf).

22. U.S. CONST. art. I, § 8, cl. 8.

23. Tyler T. Ochoa & Mark Rose, *The Anti-Monopoly Origins of the Patent and Copyright Clause*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 909, 925-27 (2002).

24. *Id.* at 925.

Would it not suffice to reserve in all cases a right to the public to abolish the privilege at a price to be specified in the grant of it?<sup>25</sup>

In recommending that the public reserve a “buyout” right, Madison clearly implied that some inventions may be considered too important for even a limited-term monopoly to be granted.<sup>26</sup> The ACLU argues this very point, asserting that gene patents violate the Constitution by slowing scientific advancement, rather than promoting the progress of science.<sup>27</sup> As the ACLU correctly pointed out, these gene monopolies “undermin[e] advances towards better treatments, cures, and more accessible, affordable genetic testing.”<sup>28</sup> Such a system clearly serves to undermine the Framers’ intent to prevent harmful monopolies and promote the progress of science.<sup>29</sup>

In contrast, the Canadian patent system seems to take a different stance on such public policy matters.<sup>30</sup> Myriad also originally attempted to assert its patent control north of the U.S. border,<sup>31</sup> but certainly did not find greener pastures. While Myriad was able to shut down its American competition through cease-and-desist and patent infringement claims,<sup>32</sup> the Canadian government, on the other hand, stated that “it is the government’s position that predictive breast and ovarian cancer tests should be available to women who require them.”<sup>33</sup> Thus, several Canadian companies continue to offer BRCA testing to this day, without fear of infringement liability.<sup>34</sup> Such a stance, of limiting monopoly power in favor of an important public health initiative, seems more in line with the original intention of the Framers.

### B. Gene Patents Heavily Reward Inventors

Rather than striking a balance between competing policy concerns, the current patent system heavily favors rewarding inventors. It is clear that the Framers struggled to balance the need for preventing monopolies with that of rewarding inventors.<sup>35</sup> According to Madison:

Monopolies though in certain cases useful ought to be granted with caution, and guarded with strictness against abuse. . . . [T]hey are

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25. *Id.* at 925-26.

26. *Id.* at 926.

27. ACLU, *supra* note 21, at 5-6.

28. *Id.* at 7.

29. Ochoa & Rose, *supra* note 23, at 925.

30. *See* Khan & Kessler, *supra* note 1, at 686.

31. *See id.* at 686.

32. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 585-86 (2013).

33. *See* Khan & Kessler, *supra* note 1, at 686.

34. *See id.*

35. Ochoa & Rose, *supra* note 23, at 925-28.

considered as compensation for a benefit actually gained to the community as a purchaser of property which the owner otherwise might withhold from public use. There can be no just objection to a temporary monopoly in these cases; but it ought to be temporary, because under that limitation a sufficient recompense and encouragement may be given. . . .<sup>36</sup>

Thus, the Framers clearly did not intend to grant monopolies on human genes. It would be absurd to contend that one's own genetic code were "property" that could be owned by a company and withheld from public use. While a particular *method* of genetic testing may satisfy the requirements of patentable subject matter, genetic sequences simply do not involve the required inventiveness to grant a monopoly.

Gene patent proponents claim that withholding protection will stifle innovation, as few will bother with the hassle and expense of research, without a guaranteed return.<sup>37</sup> This prediction is misguided, however, as academic research has long driven scientific advancement without the need for reward.<sup>38</sup> The federal government provides billions of dollars annually toward such research.<sup>39</sup> For instance, more than five million dollars of federal funding went into the discovery of the first BRCA sequence identified.<sup>40</sup> Moreover, examples like the Human Genome Project, a public collaboration which sequenced the entire human genome without patenting a single gene, illustrate the driving factor behind academic research — the sheer desire to expand, and contribute to, the cache of human knowledge.<sup>41</sup>

By contrast, Myriad's BRCA gene patents generated \$353 million for the company in 2010 alone.<sup>42</sup> The genetic monopoly, which was condoned by the Supreme Court, accounts for nearly 90% of the company's total revenue.<sup>43</sup> While the Framers' exact intent in enacting the patent clause may never be fully understood, it is hard to imagine this is the outcome that they intended. The grant of exclusive rights was intended to promote the progress of science, not to facilitate the control of genetic sequences by a clear monopoly.<sup>44</sup>

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36. *Id.* at 928 (quoting JAMES MADISON, WRITINGS 756 (Jack N. Ravoke ed. 1999)).

37. ACLU, *supra* note 21, at 8.

38. Zachary Kling, *A Myriad of Reasons: Incentives for Innovation in Genetic Research and Diagnostics Post-Myriad*, 9 BIOTECH. & PHARMACEUTICAL L. REV. 1, 28-29 (2016).

39. In 2013 alone, the National Institute of Health reported federal funding in excess of eight billion dollars for genetics research. *Id.* at 29.

40. ACLU, *supra* note 21, at 8.

41. *Id.*

42. See Khan & Kessler, *supra* note 1, at 681.

43. See *id.*

44. See Ochoa & Rose, *supra* note 23, at 925.

C. *The Gene Patent System is Detrimental to the Public Interest*

As discussed above, strictly enforced gene patents tend to create monopolies within the biotechnology field.<sup>45</sup> Due to excessive testing costs and a lack of uniform coverage amongst insurance companies, diagnostic testing remains out of reach for a significant segment of the population.<sup>46</sup> Because competitors are excluded from the marketplace, there is little incentive for cost-reduction or further innovation.<sup>47</sup> Further, the threat of patent-infringement penalties is sufficient to prevent anyone else from researching the thousands of other mutations occurring along the patented gene sequence.<sup>48</sup> Most agree that the patent system's shortcomings ultimately harm the patients, who rely on medical testing and research for any glimmer of hope that could ease their suffering.<sup>49</sup>

Myriad charges approximately \$3,000 for its BRCA1/2 diagnostic tests.<sup>50</sup> Studies have found that Myriad's testing would not be covered for nearly 50% of women with health insurance,<sup>51</sup> a figure which does not consider those without insurance, or who self-pay for fear of employment or insurance discrimination.<sup>52</sup> One genetic counselor further contends that "ninety-five percent of patients she refers for supplementary testing do not get the test because of its high cost."<sup>53</sup> It remains to be seen how current shifts in the healthcare market and coverage will affect such testing moving forward. However, a solution is unlikely if current insurance trends toward limiting costs by reducing coverage, are allowed to continue.<sup>54</sup>

In addition to the prohibitive costs faced by patients, gene patents also limit market competition.<sup>55</sup> While breakthroughs in the field have made it possible to sequence an individual's entire genetic code for as low as

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45. Khan & Kessler, *supra* note 1, at 680.

46. *Id.* at 682-85.

47. *Id.* at 680-82.

48. *Id.* at 683.

49. *Id.* at 680.

50. *Id.* at 682.

51. One study found that 42% of insured women would not be covered for BRCA ½ testing. Robert Cook-Deegan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers with Colon Cancers*, 12 GENETICS IN MED. S15, S33 (2010). Another study found that only 38% of women were able to obtain genetic testing coverage through their insurance. *Id.*

52. See Khan & Kessler, *supra* note 1, at 685.

53. See *id.* at 683.

54. Reed Abelson, *In Clash Over Health Bill, a Growing Fear of "Junk Insurance"*, N.Y. TIMES (July 15, 2017), <https://www.nytimes.com/2017/07/15/health/senate-health-care-obamacare.html>.

55. Khan & Kessler, *supra* note 1, at 683.

\$1,000,<sup>56</sup> competitors are wary of Myriad's litigious nature, and hesitant to offer results that may be viewed as infringing.<sup>57</sup> Without any alternative, patients must trust the quality and efficiency of the tests that Myriad offers.<sup>58</sup> There is no option for a second opinion, so results must simply be accepted as accurate.<sup>59</sup> Under these circumstances, Myriad effectively controls the information a patient can learn about their own genetic code.<sup>60</sup>

Gene patents also place severe limits on innovation, which is contrary to the policy behind intellectual property protection. Because Myriad holds the patents on these genes, it can "prevent anyone else from testing, studying, or even looking at the[] genes."<sup>61</sup> According to the ACLU:

[T]here are most likely additional cancer-related mutations along the BRCA1 and BRCA2 genes than those for which tests are currently conducted, including mutations that have not yet been identified. Nearly 2,000 distinct mutations and sequence variations have been found along BRCA1 and BRCA2. . . . [D]ue in part to the limitations that gene patents have placed on studying the two genes, the significance of many of these mutations is unknown.<sup>62</sup>

Myriad essentially holds the exclusive right to any mutation along the genes, and has sole control to determine which mutations are studied and tested for.<sup>63</sup> While Myriad used to share with, and contribute to, public research databases controlled by the National Institute of Health, its contributions have ceased in favor of privatizing its monopolized data.<sup>64</sup> The psychological uncertainty and confusion resulting from such limited genetic testing serve to underscore the need for abolishing gene patents.<sup>65</sup>

## II. CUSTOM AND PRACTICE HAS PREVENTED THE EVOLUTION OF PROPER PROTECTIONS

While the first patent covering DNA was issued in 1973, genes were generally only protected as an element of a claimed material or product.<sup>66</sup>

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56. The Proton Sequencer was developed by Life Technologies and can read an entire human genome for \$1,000. *Id.* at 681. Some scholars even argue that full-genome sequencing may trend as low as \$100 by the time Myriad's patent expires. *Id.* at 682.

57. *Id.* at 681-82.

58. *Id.* at 683-84.

59. *Id.*

60. ACLU, *supra* note 21, at 6.

61. *Id.* at 3.

62. *Id.* at 4 (footnote omitted).

63. Khan & Kessler, *supra* note 1, at 683.

64. *Id.*

65. *See id.* at 683-84.

66. *See* Kling, *supra* note 38, at 8.

Everything changed, however, with the Supreme Court's decision in *Diamond v. Chakrabarty* in 1980, which held as patentable "anything under the sun that is made by man."<sup>67</sup> The USPTO began granting gene patents shortly thereafter, including both human and animal genes, and by 2005, gene patents encumbered nearly 20% of the entire human genome.<sup>68</sup> While the 2013 *Myriad* decision put an end to gDNA-based gene patents, the Court deferred to concerns for the biotechnology industry, allowing the controversial cDNA-based gene patents to continue.<sup>69</sup>

At the same time, copyright law has been quick to reject the idea of genetic protection.<sup>70</sup> According to the Copyright Office, genetic sequences do not fall within one of the explicitly enumerated categories of copyright law.<sup>71</sup> Even synthetically-engineered genetic sequences "do[] not contain the minimum amount of authorship required for registration."<sup>72</sup> Effectively, the Copyright Office rejected the notion of genetic copyrights simply because genetic sequences are already patent-eligible.<sup>73</sup> However, as the trend toward weaker patent protection for biotechnology continues, it is essential that copyright law expand to compensate.

#### A. *The Current Gene Patent System Was Shaped by Industry Concerns*

The Supreme Court's decision in *Myriad* currently serves as the controlling law for DNA-related patents. In its analysis, the Court focused on the natural properties and potential patentability of gDNA, concluding that "Myriad did not create anything," and that "separating [that] a gene from its surrounding genetic material is not an act of invention."<sup>74</sup> Since patent law does not protect products of nature, *Myriad*'s discovery did not "render the . . . genes 'new . . . composition[s] of matter,' that are patent eligible."<sup>75</sup> This set a clear precedent that the discovery and isolation of a DNA sequence is not sufficient to justify patent protection.

However, the Court's discussion of cDNA was restricted to a single paragraph of its five-page analysis.<sup>76</sup> The Court merely concluded that "cDNA does not present the same obstacles to patentability as naturally

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67. *Id.* at 9.

68. *Id.* at 8-10.

69. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594 (2013).

70. *See Holman, Gustafsson, & Torrance, supra* note 16, at 103-04.

71. *See id.* at 105.

72. *Id.* at 104.

73. *See id.* at 108-09.

74. *See Myriad*, 569 U.S. at 591.

75. *Id.*

76. *Id.* at 594-95.

occurring, isolated DNA segments,”<sup>77</sup> avoiding a thorough analysis of the issue altogether. After conceding that “cDNA retains the naturally occurring exons of DNA,”<sup>78</sup> the Court found that cDNA is not a “product of nature,” because “it is distinct from the DNA from which it was derived.”<sup>79</sup> According to the Court, cDNA is based on a natural DNA sequence and retains the structure and sequence of natural DNA, but yet is somehow not itself considered a “product of nature.”<sup>80</sup>

This conclusion appears to have been justified by relying on the Myriad opposition’s concession that “cDNA differs from natural DNA in that ‘the non-coding regions have been removed.’”<sup>81</sup> Such conclusory analysis, and misplaced reliance on a concession, however, demonstrates a lack of familiarity with the subject matter. Further, Justice Scalia specifically chose to concur in the judgment and “details of molecular biology” because he was “unable to affirm those details on [his] own knowledge.”<sup>82</sup> Since the Court already found that cDNA is based on DNA, which is a product of nature, its ultimate conclusion is inconsistent with its prior reasoning.

When considered in their proper, natural context, Myriad’s cDNA sequences do not meet the requirements of patentability. cDNA is created by reverse-transcribing mRNA molecules,<sup>83</sup> which are shortened versions of the original gDNA sequence. While cDNA is different from “natural” DNA, in that the non-coding introns have been removed, the naturally-occurring exon sequences remain unaltered.<sup>84</sup> cDNA synthesis uses a well-known process that “begins with an mRNA molecule and uses the natural bonding properties of nucleotides to create a new, synthetic DNA molecule.”<sup>85</sup> Because this cDNA molecule is merely a translation of naturally-occurring DNA/mRNA, it is not sufficiently inventive to justify patent protection. Although the Court concluded that “the lab technician unquestionably creates something new when cDNA is made,” the level of creativity involved in the discovery, isolation, and translation of a particular genetic sequence, using a well-known technique, is negligible.<sup>86</sup> The Supreme Court’s decision in *Myriad*, therefore, creates a confusing precedent.

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77. *Id.* at 594.

78. *Id.* at 595.

79. *Id.*

80. *Id.*

81. *See id.*

82. *Id.* at 596 (Scalia, J., concurring).

83. Dan L. Burk, *The Curious Incident of the Supreme Court in Myriad Genetics*, 90 NOTRE DAME L. REV. 505, 508 (2014).

84. *See Myriad*, 569 U.S. at 595.

85. *Id.* at 582.

86. *Id.* at 595.

To untangle the Court's reasoning, we must consider the background against which the case was argued. According to one academic, "the most plausible rationale is that the Court hesitated to cordon off [cDNA] molecules from the incentive structure of the biotechnology industry."<sup>87</sup> Gene patents had been awarded for over thirty years prior,<sup>88</sup> leading to the birth of a robust biotechnology industry that has reached a current worth of \$414.5 billion globally.<sup>89</sup> It can be reasonably inferred that completely overturning three decades of gene patent practice would turn the industry on its head, disrupting revenues across the world.<sup>90</sup> Rather, the Supreme Court chose to "split the baby," by ending gDNA-based patents but allowing cDNA patents to continue.<sup>91</sup> However, there is hope that the Court will correct itself in the future, provided that alternate avenues of intellectual property protection become available.

### B. *Copyright Protection for Genetic Sequences*

The U.S. Copyright Office, in 1987, stated as a general policy that it would refuse copyright registration for any DNA sequences.<sup>92</sup> While this policy remains largely unchallenged, the Copyright Office recently faced a matter of first impression when a novel genetic sequence was submitted for registration.<sup>93</sup> The Office ultimately refused registration because "a claim in a DNA sequence may be far better suited for the realm of patent," which "provides reason to question whether synthetic . . . sequences are proper subject matter for copyright."<sup>94</sup> Since areas of dual, overlapping patent and copyright protection are not wholly uncommon, there is no judicial or statutory precedent by which to justify such a rejection.<sup>95</sup> To the contrary, courts have expressly found that patent, trademark, and copyright protection are not mutually exclusive of one another.<sup>96</sup> Rather than applying substantive copyright law, the Copyright Office's decision instead focused more on policy considerations and a preference toward current practice. This lack of

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87. See Burk, *supra* note 83, at 510.

88. *Id.*

89. Charlotte A. Tschider, *Metaphor After Myriad: The Effect of Legal Rhetoric on Intellectual Property Protection for Biological Sequences*, 57 IDEA: J. FRANKLIN PIERCE FOR INTELL. PROP. 519, 530 (2017).

90. See Burk, *supra* note 83, at 510.

91. *Id.*

92. See Tschider, *supra* note 89, at 558-59.

93. See Holman, Gustafsson, & Torrance, *supra* note 16, at 105.

94. *Id.* at 108-09.

95. See *id.* at 109.

96. See Kayton, *supra* note 20, at 216.

consideration for dual protection only serves to perpetuate the system of intellectual property that heavily favors rewarding innovation over facilitating public access to information.<sup>97</sup>

The primary argument against the registration of genetic sequences was their lack of inclusion in one of the eight explicitly enumerated categories of copyrightable subject matter.<sup>98</sup> However, under Section 102(a) of the Copyright Statute, these categories are meant to be illustrative examples only, and are not intended to limit protection for copyrightable works.<sup>99</sup> The Office was also concerned with its own inability to perform a search for prior-art or natural sequences.<sup>100</sup> Since prior-art searches have never been a requisite for registration of any copyrightable work, such concern is misplaced and puzzling.<sup>101</sup> The Copyright Office's final reason for refusing registration was a concern for functionality and lack of artistry.<sup>102</sup> However, the Office failed to address the differing treatment received by software code, which is highly functional and also lacks elements of artistry.<sup>103</sup> Rather, the Office's decision seems to be based primarily on a bias toward biological works.<sup>104</sup>

Since the Copyright Office has been reluctant to recognize copyright protection for genetic sequences, a judicial challenge will likely be necessary. Given the breadth of consequences associated with such a decision, a final ruling from the Supreme Court would likely be required. No inventor has thus far been willing to expend the time and money required to pursue such a path.<sup>105</sup> However, as rapid growth in the biotechnology industry continues, it is only a matter of time before copyright protection gains more widespread recognition.<sup>106</sup> As public perception begins to shift, there is hope that the Copyright Office will modify its current stance proactively.

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97. See Alex Boguniewicz, *Discovering the Undiscoverable: Patent Eligibility of DNA and The Future of Biotechnical Patent Claims Post-Myriad*, 10 WASH. J.L. TECH. & ARTS 35, 49 (2014).

98. See Holman, Gustafsson, & Torrance, *supra* note 16, at 105.

99. 17 U.S.C.A. § 102(a) (West 2006).

100. See Holman, Gustafsson, & Torrance, *supra* note 16, at 108.

101. *Id.* at 108.

102. See *id.* at 109.

103. See *id.* at 109.

104. See *id.* at 110.

105. See *id.* at 105.

106. See *id.* at 111.

C. *Gene Sequences are Copyrightable and Should be Recognized as Such*

Under the 1976 Copyright Act, the current governing law, the subject matter of copyright includes all “original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or other-wise communicated, either directly or with the aid of a machine or device.”<sup>107</sup> The statute, therefore limits protection to original works that are “fixed,” or permanent, in a “tangible medium of expression.”<sup>108</sup> While genetic sequences are not explicitly mentioned in the Copyright Act, they are clearly “fixed” as genetic code in tangible, permanent DNA.<sup>109</sup> Further, DNA would constitute a “later developed” medium of expression,<sup>110</sup> since it is capable of being perceived “with the aid of a machine or device” through DNA sequencing.<sup>111</sup> Thus, the Copyright Office’s refusal to register genetic code as a matter of principle is contrary to the body of copyright law.<sup>112</sup>

While the extension of copyright protection to genetic sequences will likely seem foreign to most, there is actually significant precedent for such an undertaking. Historically, United States copyright laws have expanded in response to technological advances.<sup>113</sup> As enacted in 1790, the original copyright statute protected only books, maps, and charts. The scope expanded over time, however, to include designs, engravings, and etchings in 1802, musical compositions in 1831, dramatic compositions in 1856, photographs in 1865, motion pictures in 1912, sound recordings in 1972,<sup>114</sup> computer software in 1980,<sup>115</sup> and semiconductor chips in 1986.<sup>116</sup> Now the Copyright Office must decide whether the explosive growth in biotechnical innovation over recent decades is sufficient to justify further expansion.

Copyright’s most recent expansion, the Semiconductor Chip Protection Act (SCPA)<sup>117</sup>, may provide the best model for implementing genetic protection. The SCPA protects semiconductor chips, which are instructions for integrated circuit designs.<sup>118</sup> Since such technology becomes outdated

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107. See Kayton, *supra* note 20, 203.

108. *Id.* at 205.

109. *See id.* at 198.

110. *Id.* at 205.

111. *Id.* at 198.

112. See Holman, Gustafsson, & Torrance, *supra* note 16, at 109.

113. See Holman, *supra* note 2, at 711-12.

114. *See id.* at 706-07.

115. *See id.* at 710.

116. Jimmy J. Zhuang, *Copyright: Better Fitting Genes*, 97 J. PAT. & TRADEMARK OFF. SOC’Y 442, 466-67 (2015).

117. *Id.*

118. 17 U.S.C.A. § 902 (West 2006).

quickly,<sup>119</sup> the protection term is limited to 10 years, as opposed to copyright's typical lifetime protection standard.<sup>120</sup> In addition, the SCPA permits reverse engineering to promote innovation in non-infringing alternatives.<sup>121</sup> Congress' ability to modify protections for a particular class of innovation is clear, and its power should be exercised to remedy the current policy issues created by gene patents.<sup>122</sup>

Similar to the controversial nature of genetic copyrights, the copyrightability of software code was also highly contested as the new field of technology emerged.<sup>123</sup> The 1976 Copyright Act was originally passed without reference to computer code, but was amended only a few years later, when the congressionally created Commission on New Technological Uses of Copyrighted Works (CONTU), found that computer programs were copyrightable not only under the terms of the 1976 Act, but also the preceding 1909 Copyright Act.<sup>124</sup> The committee, which was tasked with promoting intellectual innovation, justified its finding with the underlying copyright principle that "if the cost of duplicating information is small, then it is simple for a less than scrupulous person to duplicate it[,] . . . legal as well as physical protection for the information is a necessary incentive if such information is to be created and disseminated."<sup>125</sup> Since computer code was already copyrightable under the statute as written, the only amendment necessary was the addition of a software definition.<sup>126</sup>

Given the similarities between software and genetic code, scholars have begun to question the disparity in treatment of the two fields by copyright.<sup>127</sup> Computer software did not receive full copyright protection until 1980, when Congress accepted CONTU's recommendation to characterize software as a form of literary work,<sup>128</sup> one of the enumerated categories of copyrightable subject matter.<sup>129</sup> Computer software encodes a set of instructions directing a machine to perform a certain task and can be expressed either as intelligible source code or as a string of ones and zeros.<sup>130</sup> Genetic code, in comparison, embodies instructions directing the performance of a biological system, and

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119. See Zhuang, *supra* note 116.

120. 17 U.S.C.A. § 904 (West 2006).

121. Zhuang, *supra* note 116, at 467.

122. See *id.* at 457.

123. See Holman, *supra* note 2, at 708-12.

124. See *id.* at 709.

125. See *id.* at 709-10.

126. See *id.*

127. See Holman, Gustafsson, & Torrance, *supra* note 16, at 110.

128. See Holman, *supra* note 2, at 710.

129. See *id.*

130. See *id.* at 712.

can be expressed either as physical nucleotide sequences or in a form perceptible by humans.<sup>131</sup> The informational content in both systems can be modified predictably to alter the message ultimately being conveyed.<sup>132</sup> Thus, while other forms of biotechnological innovation may not satisfy the requirements of copyright, genetic code clearly falls within the scope of protection.<sup>133</sup>

### III. A GENETIC COPYRIGHT SYSTEM WOULD MORE PROPERLY BALANCE THE INTERESTS OF PRIVATE INVENTORS WITH THOSE OF THE GENERAL PUBLIC

Article I, Section 8, Clause 8 of the Constitution grants not only the power to award patents, but is also the basis for the U.S. Copyright system.<sup>134</sup> While genetic innovation has long been relegated solely to the domain of patents,<sup>135</sup> until recently, few had even considered the possibility of applying the protections of copyright law to genetic sequences.<sup>136</sup> As the scope of gene patents continues to narrow, however, researchers have recognized the need to consider options outside of the traditional patent system.<sup>137</sup> Barring an entirely *sui generis* form of intellectual property protection, copyright appears to be the best available option.<sup>138</sup>

Why would gene copyrights be a better option than gene patents? Compared to patents, copyrights save time and money, allowing researchers to focus on innovation rather than costly patent applications.<sup>139</sup> Copyright law is also less strict than patent law, allowing others to build on protected works without fear of an infringement action.<sup>140</sup> Finally, copyright lends itself to licensing structures that both reward innovation and promote access to information.<sup>141</sup> Thus, a genetic copyright system would serve the interests of everyone involved rather than perpetuating the public policy concerns of the current gene patent system.

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131. *See id.* at 713.

132. *See id.* at 736-37.

133. *See* Holman, *supra* note 3, at 461.

134. U.S. CONST. art. I, § 8, cl. 8.

135. *See* Holman, Gustafsson, & Torrance, *supra* note 16, at 103.

136. *See id.*

137. *See* Holman, *supra* note 3, at 443-44.

138. Zhuang, *supra* note 116, at 470-71.

139. Holman, *supra* note 3, at 444.

140. *See* Kayton, *supra* note 20, at 213.

141. Holman, *supra* note 3, at 460.

*A. The Public Would Be Best Served by a Genetic Copyright System, Which Would Promote Free Access to Information*

As discussed above, the U.S. copyright system provides greater flexibility than the current patent regime. Since copyrights are not as strictly-enforced as patents,<sup>142</sup> gene copyrights would do a better job promoting innovation than the current gene patent system. Copyright is the system on which open-source software blossomed, and scholars argue that a similar effect may be replicated in genetics.<sup>143</sup> Strict patent protection, however, has thus far frustrated any effort to bring similar collaboration to the biotechnology sector.<sup>144</sup> On the other hand, copyright protection for genetic sequences would promote cooperation and further innovation compared to the current exploitation-focused patent system.

Genetic copyrights would also promote competition. Since copyright only protects actual copying, anyone may use any sequence, provided they discovered it by independent means, rather than using a protected sequence as a template.<sup>145</sup> Not only would this reduce the monopoly power currently enjoyed by the biotech industry, but would also promote both cost and quality-control measures. Further, the Fair Use Doctrine grants infringement exemptions for certain scholarly or transformative uses of copyrighted works, offering yet another route to pursue innovation.<sup>146</sup> The use of any protected sequence, therefore, could receive immunity from infringement liability if deemed sufficiently important to the public interest.

In addition to the aforementioned benefits, a genetic copyright regime also offers innovation-friendly licensing structures. Under a compulsory licensing system, such as that used by the music industry, anyone can use any protected sequence by paying a designated fee.<sup>147</sup> For example, under such a structure, anyone could offer genetic testing using Myriad's BRCA sequences, provided they pay a statutory minimum licensing fee for each use. Such licensing systems promote further innovation, while also allowing researchers to recoup initial costs and even turn a profit. This "per-use" fee would also provide a reward for innovative efforts directly proportional to a sequence's perceived importance. While useless sequences will undoubtedly generate little return, those with life-altering potential are likely to benefit substantially. Thus, gene copyrights would promote further competition and

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142. See Kayton, *supra* note 20, at 213-14.

143. See Holman, *supra* note 2, at 737.

144. See Holman, *supra* note 3, at 460.

145. See Kayton, *supra* note 20, at 194.

146. See Holman, *supra* note 2, at 738.

147. See U.S. COPYRIGHT OFFICE, COMPULSORY LICENSE FOR MAKING AND DISTRIBUTING PHONORECORDS 1 (2018), <https://www.copyright.gov/circs/circ73.pdf>.

innovation while still allowing researchers to retain general control over the commercialization of their inventions.

*B. A System of Copyright Protection Would Better Serve Inventors, Allowing Them to Focus on Innovation Rather than Exploitation*

Copyrights offer a cheaper and faster alternative for innovators to protect their intellectual property compared to the process of obtaining a patent.<sup>148</sup> Prosecution of a single patent typically requires 30-40 months<sup>149</sup> and at least \$10,000.<sup>150</sup> By comparison, copyright protection is instilled immediately upon a work's creation,<sup>151</sup> and registration only becomes necessary to commence an infringement action.<sup>152</sup> For a small or struggling corporation, these distinctions can mean the difference between success and failure. A copyright system, therefore, would allow researchers to put more time and money toward innovation rather than red-tape.

A copyright system also aligns with researchers' need to publish findings as soon as possible. Due to fierce competition within the research industry, scientists must publish findings as soon as possible or risk getting "scooped"<sup>153</sup> by a rival group.<sup>154</sup> This rush to publish, however, is wholly incompatible with the current gene patent regime, which can take years to grant protection.<sup>155</sup> Since copyright instills protection immediately upon creation, researchers could safely publish their findings the very same day.<sup>156</sup> Copyright registration only becomes necessary in order to pursue legal action in response to infringement.<sup>157</sup>

Finally, a genetic copyright system would provide inventors with beneficial options for remedy in response to infringement. Copyright law is more amenable to injunctions, allowing innovators to assert their legal rights prior to an official judicial ruling.<sup>158</sup> While statutory damages up to \$30,000

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148. See Kayton, *supra* note 20, at 196.

149. Holman, *supra* note 3, at 456-57.

150. *Id.* at 444.

151. See Kayton, *supra* note 20, at 198.

152. See *id.*

153. "Scooped" means that a competitor rushed to publish a very similar study first, lessening the subsequent scientific impact of a given discovery. Sam Schwazkopf, *It's Not the End of the World If Your Research Gets "Scooped"*, WORLD.EDU (April 9, 2016), <http://world.edu/not-end-world-research-gets-scooped/>.

154. See Leslie Roberts, *The Rush to Publish*, 251 SCIENCE 260 (1991).

155. See Holman, *supra* note 3, at 456-57.

156. See U.S. COPYRIGHT OFFICE 1, 4, 7.

157. *Id.* at 5.

158. 17 U.S.C.A. § 502 (West 2006).

are available,<sup>159</sup> a copyright owner may instead seek to recover the infringer's profits, in addition to his own damages.<sup>160</sup> If the infringement is willful, the court may, in its discretion, increase the damages award up to \$150,000.<sup>161</sup> Moreover, the court can impound all infringing articles during litigation, as well as any means for manufacture or reproduction.<sup>162</sup> If convicted of infringement, anything impounded during trial may be ordered destroyed as part of a final judgment or decree.<sup>163</sup> A genetic copyright system, therefore, would protect inventor's interests better than the current gene patent regime.

*C. Achieving a Proper Balance Between Public and Private Interests is Key Toward Promoting the Progress of Science*

While gene patents are not the answer, it is generally recognized that some form of intellectual property protection is necessary to promote continued innovation. Failure to properly safeguard the fruits of such innovation would lead not only to lost research investments,<sup>164</sup> but to the eventual downfall of a \$400 billion industry.<sup>165</sup> On the other hand, the current patent-centric framework has led to monopolistic practices and has stifled innovation.<sup>166</sup> Reaching a balance between rewarding innovation and promoting access to information is key to facilitating the progress of biotechnology. As gene patents continue to decline, researchers must push for an alternative form of protection to fill the gaps left behind.

As the needs of the biotechnology industry continue to evolve, the intellectual property system must also evolve to accommodate it. While new genetic discoveries remain essential, the field has shifted more toward synthetic biology, or "genetic engineering."<sup>167</sup> Where once the mere discovery of a gene sequence was sufficient, today, researchers actively manipulate DNA to create novel "biological machines."<sup>168</sup> With each additional genetic alteration, the amount of proprietary information grows, and the need for flexible intellectual property protection along with it. The current patent regime is ill-suited to handle this exponential growth, and researchers will need to look elsewhere for protection.

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159. 17 U.S.C.A. § 504 (West 2006).

160. *Id.*

161. *Id.*

162. 17 U.S.C.A. § 503 (West 2006).

163. *Id.*

164. *See* Tschider, *supra* note 89, at 531.

165. *See id.* at 530.

166. *See* Khan & Kessler, *supra* note 1, at 680-82.

167. *See* Holman, *supra* note 3, at 419.

168. *Id.* at 419-20.

Given the biotech industry's history, continued growth and evolution should be expected. At the same time, expansion of the current gene patent system would lead to crippling freedom to operate concerns and stifled innovation.<sup>169</sup> Moreover, issues with personalized genetics and control over one's own DNA sequences are destined to arise as the advance of synthetic biology continues. In fact, some companies are already seeking to purchase the rights to a person's individual genetic sequence, though the validity of such transfer is questionable.<sup>170</sup> While future issues cannot be accurately predicted, they can be anticipated by the installation of a flexible intellectual property system, such as the one substantive copyright law provides.

#### CONCLUSION

The public policy concerns at issue in *Myriad* underscore the current patent regime's weaknesses in protecting genetic sequences. The genetic monopolies currently being awarded are harmful both to patients and innovation. The Supreme Court's *Myriad* decision, which attempted to "split the baby," by protecting cDNA but not gDNA, only serves to exacerbate the underlying issue.<sup>171</sup> A gene copyright regime, on the other hand, would rectify these issues and allow innovation to flourish. Such a transition may seem unnatural to many at first but is the best path toward bringing the policy concerns surrounding genetic innovation into proper balance.

Although a genetic copyright system would solve the quagmire created by gene patents, a transition is unlikely to happen anytime soon. Software protection, for example, was only extended after decades of debate.<sup>172</sup> Given the Copyright Office's current reluctance to extend registration to even novel genetic sequences, a judicial challenge will likely be necessary to overcome custom and practice.<sup>173</sup> Further, many specifics remain largely up for debate and Congress will likely require several years to reach a comprehensive solution. While copyright provides the basic framework for more balanced protection of genetic innovation, this protection must be tailored specifically toward biotechnology in order to achieve the desired result. The road ahead is long and arduous, however, but reaching a proper balance between

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169. *See id.* at 447.

170. As part of their terms of service, Ancestry.com requires users to permanently sign over ownership of their entire genetic sequence. Joel Winston, *Ancestry.com Takes DNA Ownership Rights from Customers and Their Relatives*, THINK PROGRESS (May 17, 2017, 7:54 PM), <https://thinkprogress.org/ancestry-com-takes-dna-ownership-rights-from-customers-and-their-relatives-dbafeed02b9e/>.

171. *Ass'n Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

172. *See* Holman, *supra* note 2, at 709-11.

173. *See* Holman, Gustafsson, & Torrance, *supra* note 16, at 111.

protection and innovation is certainly a worth-while endeavor, especially when human lives are at stake.

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