

# A MYRIAD OF REASONS TO CELEBRATE: WHY THE INVALIDATION OF ISOLATED DNA PATENTS IS A VICTORY FOR PERSONAL PROPERTY RIGHTS

*“[T]here’s been a near-universal ‘What??!’ when people hear that it’s legal for someone to own the rights to our DNA.”*

—Sharon Begley<sup>1</sup>

## INTRODUCTION

Your identity has value, and sometimes that value belongs to you. States may protect, for example, the commercial value of your name, voice, signature, photograph, and likeness.<sup>2</sup> A handful of states have also considered protecting the value of personal DNA.<sup>3</sup> Extending the same protections that we enjoy in our physical characteristics to our genetic makeup would appear to be a logical step because our genetic material is “uniquely linked to our identity as a person.”<sup>4</sup> Indeed, “[e]very feature of

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1. Sharon Begley, *Who Owns Your DNA?: Why Patenting Genes is a Bad Idea*, DAILY BEAST (Feb. 3, 2010, 7:00 PM), <http://www.thedailybeast.com/newsweek/2010/02/03/who-owns-your-dna.html>.

2. *E.g.*, CAL. CIV. CODE § 3344(a) (West 2007) (“Any person who knowingly uses another’s name, voice, signature, photograph, or likeness, in any manner, on or in products, merchandise, or goods . . . without such person’s prior consent . . . shall be liable for any damages sustained by the person or persons injured as a result thereof.”); OKLA. STAT. ANN. tit. 12, § 1449(A) (West 2010) (same); N.Y. CIV. RIGHTS LAW § 51 (McKinney 2009) (“Any person whose name, portrait, picture or voice is used within this state for advertising purposes or for the purposes of trade without the written consent first obtained . . . may maintain an equitable action . . . to prevent and restrain the use thereof; and may also sue and recover damages for any injuries sustained . . . .”); RESTATEMENT (SECOND) OF TORTS § 652C cmt. a (1977) (identifying the tort action against one who appropriates another’s name or likeness as a “property right, for the exercise of which an exclusive license may be given to a third person”).

3. *Genetic Privacy Laws*, NAT’L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/issues-research/health/genetic-privacy-laws.aspx> (last updated Jan. 2008) (identifying five states that define genetic information as personal property and one that also defines genetic material as personal property); *see also* H.B. 1260, 2012 Legis. Assemb., 87th Sess. § 2 (S.D. 2012), *available at* <http://legis.state.sd.us/sessions/2012/Bills/HB1260P.pdf> (“All DNA, genetic information, or results of any genetic test, as related to health benefit plans, are the sole property of the person from whom it was derived.”); S. 1080, 187th Gen. Court, Reg. Sess. § 1 (Mass. 2011), *available at* <http://www.malegislature.gov/Bills/187/Senate/S01080> (“[G]enetic information is a unique product of an individual’s body, the unauthorized use of which interferes with both privacy rights and property interests of that individual.”); H. 368, 2011–2012 Leg., Reg. Sess. § 4 (Vt. 2011), *available at* <http://www.leg.state.vt.us/docs/2012/bills/Intro/H-368.pdf> (“[G]enetic material shall be considered real property subject to one’s individual control and dominion in accordance with generally held precepts of property law in Vermont.”).

4. Katherine Booth, Column, *Isolated DNA Patents: Incentivizing Medical Research or Selling Human Identity?*; Association for Molecular Pathology v. U.S. Patent and Trademark Office, 40

our physical being is coded for by DNA, and many scientists would argue that virtually every aspect of humanity is similarly encoded.”<sup>5</sup> In other words, the physical characteristics to which we claim a property right often manifest our underlying genetic identity.

But why have so few lawmakers considered extending property rights to DNA? One issue appears to have been the risk of preemption by federal patent law. Fortunately, the United States Supreme Court removed this hurdle in *Association for Molecular Pathology v. Myriad*, holding that isolated human DNA is not patentable.<sup>6</sup> If the patent holder—in that case, Myriad Genetics, Inc.—had prevailed, then it would have retained the power to exclude others from making, using, or selling the isolated DNA molecules specified in its patents.<sup>7</sup> How exactly did this federal intellectual property right hinder state efforts to define DNA as personal property? Some commentators have suggested that isolated DNA patents granted a right over “our DNA.”<sup>8</sup> From a strictly chemical perspective, isolated DNA is distinguishable from “our DNA.” However, tension would have existed between DNA patent rights and personal property rights because current sequencing technology potentially infringed some isolated DNA patents. Furthermore, if we look beyond the chemical nature of the patented molecules and consider isolated DNA patents as rights over the human genome itself, it becomes clear that these patent rights would have significantly circumscribed any personal property right to DNA. Although the “metes and bounds”<sup>9</sup> of isolated DNA patents covered molecules that did not exist in our bodies, the informational content of those molecules was identical to the information stored within our own DNA.

This Note examines the right to individual DNA within intellectual and personal property law and proceeds in five parts. Part I of this Note provides a brief overview of the structure and function of DNA. Part II discusses the history of DNA patents and the Supreme Court’s recent decision invalidating isolated DNA patents. Part III explores current state efforts to define DNA as personal property, including a summary of both

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J.L. MED. & ETHICS 413, 416 (2012).

5. R. GRANT STEEN, *DNA & DESTINY: NATURE AND NURTURE IN HUMAN BEHAVIOR* 3 (1996).

6. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

7. U.S. Patent Act, 35 U.S.C. § 271(a) (2006).

8. *E.g.*, Begley, *supra* note 1; Steven Salzberg, *Private Companies Own Your DNA—Again*, FORBES (July 31, 2011, 5:06 PM), <http://www.forbes.com/sites/stevensalzberg/2011/07/31/private-companies-own-your-dna-again>; *see also* Booth, *supra* note 4, at 414 (“[I]f individuals have property rights in their own DNA, including DNA extracted from their body, DNA patents infringe on personal property rights.”).

9. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989).

enacted and proposed laws. Part IV analyzes the complex interactions between intellectual and personal property rights to human DNA, including the effects of isolated DNA patents on whole genome sequencing. Finally, Part V considers the informational rights conferred on the patent holder and why those rights would have circumscribed personal property rights. Considering the informational character of human DNA and the rights conferred by both federal patent law and state property law, this Note concludes that gene patents would have substantially limited the exercise of personal property rights to DNA. By invalidating isolated DNA patents, the Supreme Court has finally given state lawmakers an opportunity to fill the genetic gap in personal property law.

### I. DNA: THE BLUEPRINT FOR PROTEIN SYNTHESIS<sup>10</sup>

Although DNA participates in the synthesis of multiple biological products, for simplicity I will focus exclusively on its role in protein synthesis.<sup>11</sup> Proteins play many essential roles within the body,<sup>12</sup> and the genetic sequence encoding each protein carries crucial information about the organism from which it is derived.<sup>13</sup> To understand this relationship, one must take a close look at the structure and function of DNA.

#### *A. Structure of DNA*

DNA, or deoxyribonucleic acid, consists of two strands of repeating units called nucleotides.<sup>14</sup> Each nucleotide is composed of the sugar deoxyribose, a phosphate group, and one of four nitrogenous bases: adenine (A), thymine (T), cytosine (C), or guanine (G).<sup>15</sup> The sugar and phosphate groups form the “backbone” of each strand of nucleotides.<sup>16</sup> Relatively weak bonds between the nitrogenous bases hold together the two strands.<sup>17</sup>

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10. This Note explores only the most basic aspects of DNA and protein structure and function. See SANGEETA MALVEE, *PRINCIPLES OF GENETICS* (2010), for a more thorough analysis.

11. Other gene products include ribosomal ribonucleic acid (rRNA) and transfer ribonucleic acid (tRNA), which participate in the process of transcription. *Id.* at 187, 214.

12. Proteins play a wide variety of roles in the human body, including protecting the body from pathogens; carrying messages between different cells, tissues, and organs; providing structural support for cells and enabling body movement; and transporting and storing other materials. See *infra* Part I.B.; *What Are Proteins and What Do They Do?*, U.S. NAT'L LIBR. OF MED., NAT'L INST. OF HEALTH (Nov. 4, 2013), <http://ghr.nlm.nih.gov/handbook/howgeneswork/protein>.

13. MALVEE, *supra* note 10, at 1, 119.

14. *Id.* at 110.

15. *Id.* at 111.

16. *Id.*

17. *Id.* at 111–12.

An adenine unit on one strand will only bind to a thymine unit on the other strand, and vice versa; cytosine, likewise, will only bind to guanine, and vice versa.<sup>18</sup> Thus, the sequence of nucleotides on one strand is complementary to the sequence on the other strand.<sup>19</sup> For example, if one strand contains the sequence CATG, then the complementary strand will contain the sequence GTAC.

The two strands “entwine like vines” to form a double helix structure.<sup>20</sup> Within cells, DNA is found in compact structures called chromosomes.<sup>21</sup> For the purposes of this Note, it will suffice to adopt the Federal Circuit’s mercifully concise explanation of chromosomes: “Chromosomes are complex structures comprising a single extended DNA molecule wrapped around proteins called histones . . . .”<sup>22</sup> The DNA molecule within each chromosome comprises millions of pairs of nucleotides.<sup>23</sup> Within eukaryotic organisms, such as plants and animals, chromosomes are located in a cellular structure called the nucleus.<sup>24</sup> Human cells contain twenty-three pairs of chromosomes.<sup>25</sup> The largest human chromosome, Chromosome 1, contains 220 million pairs of nucleotides.<sup>26</sup>

### B. Function of DNA

DNA contains “instructions for constructing and operating an organism.”<sup>27</sup> These instructions exist in nucleotide sequences called genes.<sup>28</sup> A gene is typically thousands of nucleotides long and often contains the instructions for one or more proteins.<sup>29</sup> The human genome consists of approximately 22,000 genes.<sup>30</sup> The two primary processes through which

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18. *Id.* at 112.

19. *Id.*

20. *Id.* at 111.

21. *Id.* at 110. A complete discussion of the composition of chromosomes is beyond the scope of this summary.

22. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1313 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

23. *Id.*

24. *MALVEE*, *supra* note 10, at 110.

25. *Ass’n for Molecular Pathology*, 689 F.3d at 1313.

26. *MALVEE*, *supra* note 10, at 110.

27. *Id.* at 1–2.

28. *Id.* at 2, 16.

29. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 194 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

30. *Ass’n for Molecular Pathology*, 689 F.3d at 1310.

the information in a gene is used to synthesize a protein are called transcription and translation.<sup>31</sup>

### 1. Transcription

During transcription, the DNA in a gene is “transcribed” into a similar molecule called ribonucleic acid (RNA).<sup>32</sup> Like DNA, RNA consists of a sequence of nucleotides.<sup>33</sup> However, unlike DNA, RNA is single-stranded, and its nucleotides contain the sugar ribose instead of deoxyribose.<sup>34</sup> The sequence of nucleotides in DNA serves as the blueprint for the RNA molecule.<sup>35</sup> RNA is transcribed from DNA one nucleotide at a time, forming a growing chain that is complementary to its DNA blueprint.<sup>36</sup> Enzymes then process the transcribed RNA to form the final RNA product.<sup>37</sup> Some RNA products, called messenger RNA (mRNA), carry the information encoded in DNA to the site of protein synthesis.<sup>38</sup> The information in mRNA is then “translated” into a protein.<sup>39</sup>

### 2. Translation

The sequence of nucleotides in mRNA corresponds to the sequence of amino acids in its encoded protein.<sup>40</sup> Processed mRNA consists of three-nucleotide units called “codons.”<sup>41</sup> Each codon corresponds to one of the twenty different amino acids or a “stop” signal to indicate the end of protein synthesis.<sup>42</sup> This relationship between codons and amino acids is known as the “genetic code.”<sup>43</sup> During translation, another type of RNA, transfer RNA (tRNA), helps translate the nucleotide sequence in mRNA into its

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31. MALVEE, *supra* note 10, at 16.

32. *Id.* at 16, 102.

33. *Id.* at 102.

34. *Id.* at 104.

35. *Id.* at 187.

36. *Id.* at 188. Note that RNA contains the nitrogenous base uracil (“U”) instead of thymine. *Id.* Thus, if a DNA sequence is CAT, its RNA complement will be GUA, not GTA.

37. *Id.* at 102.

38. *Id.* at 103, 105–06.

39. *Id.* at 106.

40. *Id.* at 105.

41. *Id.* at 106.

42. *Id.* at 119; Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1312 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom.* Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013). Note that there are 64 distinct codons and only 20 amino acids, so most amino acids correspond to more than one codon. MALVEE, *supra* note 10, at 119.

43. MALVEE, *supra* note 10, at 119.

corresponding amino acid sequence.<sup>44</sup> Each tRNA molecule carries a specific amino acid and contains a three-nucleotide “anticodon” region, which binds to complementary codons in the mRNA molecule.<sup>45</sup> Each codon on the mRNA molecule is read in order, starting with the “start codon,” which is commonly AUG.<sup>46</sup> When a tRNA molecule matches the codon being read, it adds its specific amino acid to the growing amino acid chain.<sup>47</sup> Translation terminates when the ribosome reaches a “stop” codon.<sup>48</sup> The completed chain of amino acids then folds into a three-dimensional shape and becomes a functional protein molecule.<sup>49</sup>

In summary, DNA is transcribed into RNA, which is often (but not always) translated into proteins. Proteins play various structural and functional roles within an organism. Thus, DNA contains information that ultimately influences the traits of an organism.<sup>50</sup>

## II. THE UN-PATENTABILITY OF ISOLATED DNA

The United States Patent and Trademark Office (PTO) has been granting DNA patents for over 30 years.<sup>51</sup> This past June, the Supreme Court finally declared that isolated DNA—that is, DNA separated from the rest of the chromosome but retaining its naturally occurring sequence of nucleotides—is not patent-eligible because it is a product of nature.<sup>52</sup>

### A. The History of DNA Patents

Patent protection has existed in the United States since the ratification of the Constitution in 1788.<sup>53</sup> Article I, Section 8 empowers Congress 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>54</sup> Congress passed the first patent statute in

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44. *Id.* at 106.

45. *Id.* at 106, 161–62.

46. *Id.* at 204.

47. *Id.* at 106, 119.

48. *Id.* at 161.

49. *Id.* at 90.

50. *Id.* at 1–2, 119.

51. See Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 19, 19 (2011) (noting that the United States granted the first human “gene patents” in 1982).

52. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111, 2116–19 (2013). However, the Supreme Court held that a type of synthetic DNA, known as complementary DNA or cDNA, is not a product of nature as it contains a sequence of DNA not found in nature. *Id.* at 2119.

53. ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 125 (6th ed. 2012).

54. U.S. CONST. art. I, § 8, cl. 8.

1790.<sup>55</sup> The Patent Act embodies the current scope of patent rights.<sup>56</sup> Section 101 of the Patent Act provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>57</sup> The PTO reviews patent applications to determine whether they meet the requirements of the Patent Act.<sup>58</sup>

The Supreme Court considered the patent eligibility of biological materials in *Diamond v. Chakrabarty*.<sup>59</sup> In that case, Chakrabarty, a microbiologist, attempted to patent a genetically engineered bacterium.<sup>60</sup> The patent examiner rejected Chakrabarty’s claim to the bacterium, asserting that microorganisms are “products of nature” and that living things are not patentable subject matter under Section 101.<sup>61</sup> The Court agreed that “[t]he laws of nature, physical phenomena, and abstract ideas” are not patentable.<sup>62</sup> By a vote of 5-4, however, the Court concluded that Chakrabarty’s microorganism plainly qualified as patentable subject matter because it was “a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’”<sup>63</sup>

The first gene patents were granted shortly thereafter.<sup>64</sup> In 2001, the PTO formally published its long-standing determination that isolated DNA is patent-eligible.<sup>65</sup> Responding to public comments asserting that genes are not patent-eligible subject matter, the PTO observed that

- (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA

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55. MERGES ET AL., *supra* note 53, at 126 (citing Patent Act of 1790, Ch. 7, 1 Stat. 109–12 (Apr. 10, 1790)).

56. 35 U.S.C. §§ 1–376 (2006).

57. *Id.* § 101.

58. MERGES ET AL., *supra* note 53, at 128.

59. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

60. *Id.*

61. *Id.* at 306.

62. *Id.* at 309 (citing *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

63. *Id.* at 309–10 (alteration in original) (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

64. See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1333 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (“In the early 1980s, the [PTO] granted the first human gene patents.” (citing Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 19 (2010)).

65. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092–93 (issued Jan. 5, 2001).

molecule does not occur in that isolated form in nature [and] (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.<sup>66</sup>

It is estimated that the PTO issued more than 2,600 isolated DNA patents.<sup>67</sup>

### *B. Is Isolated DNA Patentable Subject Matter?*

On May 12, 2009, the Association for Molecular Pathology and various other organizations, medical professionals, researchers, and medical patients brought suit against the PTO, Myriad Genetics, and patent holders who had granted Myriad an exclusive license to use their patented DNA. These plaintiffs asserted, *inter alia*, that the isolated DNA patents the PTO had issued to Myriad and the other patent holders were invalid because they covered products of nature.<sup>68</sup> The district court granted, in part, the plaintiffs' motion for summary judgment.<sup>69</sup> The court noted that patent-eligible subject matter must be "markedly different" from a product of nature.<sup>70</sup> It explained that "[i]n light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between [the] native . . . DNA and the isolated . . . DNA claimed in the patents-in-suit render the claimed DNA 'markedly different.'"<sup>71</sup>

The Federal Circuit reversed the district court's grant of summary judgment with regard to the isolated DNA patents.<sup>72</sup> In reaching this decision, the Federal Circuit focused on the chemical nature of isolated DNA, observing that the claimed isolated DNA molecules have to be "chemically cleaved" from the rest of the DNA molecule.<sup>73</sup> "[W]hen cleaved," the court noted, "an isolated DNA molecule is not a purified form

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66. *Id.* at 1093.

67. *Ass'n for Molecular Pathology*, 689 F.3d at 1333.

68. Complaint at 3–14, 29–30, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 193 (S.D.N.Y. 2010) (No. 1:09-cv-04515), ECF No. 1.

69. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 238. The court dismissed various constitutional claims. *Id.* at 237–38.

70. *Id.* at 222 (internal quotation marks omitted).

71. *Id.* at 229.

72. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1358 (Fed. Cir. 2011), *reh'g denied* (Sept. 13, 2011), *reh'g denied* (Sept. 16, 2011), *cert. granted, judgment vacated sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (U.S. 2012) and *opinion vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 2012). The Federal Circuit also reversed the district court's grant of summary judgment regarding a method patent. *Id.* This patent issue is not relevant to the discussion of isolated DNA.

73. *Id.* at 1352.



of a natural material, but a distinct chemical entity.”<sup>74</sup> The court rejected the plaintiffs’ argument that the shared informational content of isolated and naturally occurring DNA renders the patents invalid.<sup>75</sup> According to the court, the informational content of DNA is irrelevant to the fact that isolated DNA molecules are chemically distinct.<sup>76</sup>

The Supreme Court vacated and remanded the decision to the Federal Circuit for further consideration in light of the Court’s decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>77</sup> On remand, the Federal Circuit affirmed its decision with respect to isolated DNA, noting that *Mayo* was not controlling on that issue.<sup>78</sup> On November 30, 2012, the Supreme Court granted the plaintiffs’ petition for writ of certiorari to consider, yet again, the patentability of human genes.<sup>79</sup>

In a unanimous decision penned by Justice Thomas, the Court reversed the Federal Circuit’s decision with respect to isolated DNA, holding that isolated DNA is, indeed, a product of nature.<sup>80</sup> The Court first noted that “Myriad did not create or alter any of the genetic information encoded in the [patented] genes . . . . Instead, Myriad’s principal contribution was uncovering the precise location and genetic sequence of the [patented] genes within chromosomes 17 and 13.”<sup>81</sup> But extensive effort alone, the Court explained, would not transform Myriad’s discovery into a patent-eligible composition of matter.<sup>82</sup> Nor was the Court persuaded by the Federal Circuit’s chemical-based interpretation of Myriad’s claims:

Myriad’s claims [are not] saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby

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74. *Id.*

75. *Id.* at 1353.

76. *Id.*

77. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794, 1794 (2012). In *Mayo*, the Supreme Court evaluated method patents concerning the use of thiopurine drugs in the treatment of autoimmune diseases. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294–95 (2012). The patents focused on the relationships between concentrations of certain metabolites in the blood and the safety and effectiveness of a dosage of a thiopurine drug. *Id.* at 1296. The Court held that the steps in the patent were not sufficient to transform “unpatentable natural correlations into patentable applications of those regularities.” *Id.* at 1298.

78. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1325 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

79. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694, 695 (2012); *Petition for Writ of Certiorari, Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (No. 12-398), 2012 WL 4502947.

80. *Myriad*, 133 S. Ct. at 2111.

81. *Id.* at 2116.

82. *Id.* at 2117–18.

creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the [patented] genes.<sup>83</sup>

In concluding that Myriad's isolated DNA claims covered products of nature, the Court effectively voided the approximately 2,600 isolated DNA patents issued by the PTO since *Chakrabarty*.<sup>84</sup> Whether knowingly or not, it simultaneously removed a significant hurdle for legislative efforts to define DNA as personal property.

### III. STATE EFFORTS TO DEFINE DNA AS PERSONAL PROPERTY

Three states—Massachusetts,<sup>85</sup> South Dakota,<sup>86</sup> and Vermont<sup>87</sup>—have recently considered legislation that would define DNA as personal property. Five states have already defined genetic information as personal property,<sup>88</sup> but these property interests appear to be either too narrow<sup>89</sup> or too ambiguous<sup>90</sup> to provide actionable rights. To understand what the three proposed genetic property laws would do—or would have done—and why, it will help to survey the genetic property laws in each of these five states.

#### A. The Scope of Current State Genetic Property Rights

The five states that define genetic information as personal property are Alaska, Colorado, Florida, Georgia, and Louisiana.<sup>91</sup> Three of these five states may have narrowly limited this right to issues of insurance coverage. The remaining two states have not specifically declared whether this

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83. *Id.* at 2118.

84. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1333 (Fed. Cir. 2012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (internal quotation marks omitted) (noting that the PTO has issued more than 2,600 "isolated DNA" patents over the past twenty-nine years).

85. S. 1080, 187th Gen. Court, Reg. Sess. § 1 (Mass. 2011), *available at* <http://malegislature.gov/Bills/187/Senate/S1080>.

86. H.B. 1260, 2012 Legis. Assemb., 87th Sess. § 2 (S.D. 2012), *available at* <http://legis.state.sd.us/sessions/2012/Bills/HB1260P.pdf>.

87. H. 368, 2011–2012 Leg., Reg. Sess. § 1 (Vt. 2011), *available at* <http://www.leg.state.vt.us/docs/2012/bills/Intro/H-368.pdf>.

88. *See infra* Part III.A.

89. *See infra* Parts III.A.2, III.A.4–5.

90. *See infra* Parts III.A.1, III.A.3.

91. NAT'L CONFERENCE OF STATE LEGISLATURES, *supra* note 3.

property right incorporates common law causes of action, such as conversion. Courts may be unwilling to enforce such broad property rights over genetic information without the express approval of the state legislature.

### 1. Alaska

Alaska's genetic testing statute provides, in pertinent part, that

a person may not collect a DNA sample from a person, perform a DNA analysis on a sample, retain a DNA sample or the results of a DNA analysis, or disclose the results of a DNA analysis unless the person has first obtained the informed and written consent of the person, or the person's legal guardian or authorized representative, for the collection, analysis, retention, or disclosure . . . .<sup>92</sup>

The statute further declares that "a DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed."<sup>93</sup> The statute contains exceptions for DNA identification registration to support criminal justice services, law enforcement purposes, determining paternity, screening newborns, and emergency medical treatment.<sup>94</sup> Whether this law is meant to incorporate common law property rights is unclear.<sup>95</sup> As of 2011, no one had been prosecuted under this law.<sup>96</sup>

### 2. Colorado

Colorado law provides that "[g]enetic information is the unique property of the individual to whom the information pertains."<sup>97</sup> However, the statute later clarifies that the "intent of this section is to prevent information derived from genetic testing from being used to deny access to

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92. ALASKA STAT. § 18.13.010(a)(1) (2012).

93. *Id.* § 18.13.010(a)(2).

94. *Id.* § 18.13.010(b).

95. *Cf.* Eriq Gardner, *Gene Swipe: Few DNA Labs Know Whether Chromosomes Are Yours Or If You Stole Them*, A.B.A. J. (Aug. 1, 2011, 3:40 AM), [http://www.abajournal.com/magazine/article/gene\\_swipe\\_few\\_dna\\_labs\\_know\\_whether\\_chromosomes\\_are\\_yours\\_or\\_if\\_you\\_stole/](http://www.abajournal.com/magazine/article/gene_swipe_few_dna_labs_know_whether_chromosomes_are_yours_or_if_you_stole/) (observing that other legislative proposals would go even further than this statute because "[t]hey would not only mandate consent for the collection and use of DNA but also spell out that individuals have a right to privacy with respect to their genetic information").

96. *Id.*

97. COLO. REV. STAT. § 10-3-1104.7(1)(a) (2012).

group disability insurance or long-term care insurance coverage.”<sup>98</sup> Thus, the scope of this statute may be confined only to issues concerning insurance coverage.<sup>99</sup>

### 3. Florida

Florida law provides that the results of DNA analysis “are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested.”<sup>100</sup> The statute contains exceptions for criminal prosecution, determining paternity, and compiling a DNA database for criminal investigations.<sup>101</sup> Violation of this provision constitutes a misdemeanor.<sup>102</sup> The scope of this law is unclear, especially with respect to common law causes of action. In *Greenberg v. Miami Children’s Hospital Research Institute, Inc.*, a federal court rejected the claim that this statute confers a right to recover for conversion.<sup>103</sup> In that case, various individuals and non-profit organizations brought suit against a research institution that had used the plaintiffs’ DNA samples to isolate and patent the gene responsible for Canavan disease, a degenerative condition that affects the metabolism of aspartic acid.<sup>104</sup> The plaintiffs alleged that they provided their DNA samples and confidential information “with the understanding and expectations that such samples and information would be used for the specific purpose of researching Canavan disease and identifying mutations in the Canavan disease which could lead to carrier detection within their families and benefit the population at large.”<sup>105</sup> The plaintiffs claimed, among other things, that they never relinquished their property interest in their genetic information to the defendants.<sup>106</sup> The court rejected this claim, observing that even if Florida Statute Section 760.40

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98. *Id.* § 10-3-1104.7(1)(d).

99. *Id.*; NAT’L CONFERENCE OF STATE LEGISLATURES, *supra* note 3.

100. FLA. STAT. ANN. § 760.40(2)(a) (West 2010) (citing FLA. STAT. ANN. § 943.325 (West 2006) (detailing the use of DNA databases in criminal investigations)).

101. *Id.*

102. *Id.* § 760.40(2)(b).

103. *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1075 (S.D. Fla. 2003).

104. *Id.* at 1066–67; *Canavan Disease*, NAT’L CTR. FOR BIOTECHNOLOGY INFO., NAT’L INST. OF HEALTH, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002553/> (last updated Nov. 14, 2011).

105. *Greenberg*, 264 F. Supp. 2d at 1067 (quoting Complaint at 7, *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 208 F. Supp. 2d 918 (N.D. Ill. 2002) (No. 00-C-6779), 2000 WL 34304606) (internal quotation marks omitted).

106. *Id.* at 1074.

does create a property right in genetic material donated for medical research purposes, it does not clearly confer a property right for conversion.<sup>107</sup>

#### 4. Georgia

Georgia's genetic testing laws provide that "[g]enetic information is the unique property of the individual tested."<sup>108</sup> The purpose of these laws is to prevent insurance companies and other payors from using genetic information to deny access to accident and sickness insurance.<sup>109</sup> Thus, like Colorado's genetic information statute, these laws may be limited to the narrow issue of insurance coverage. Georgia's laws also expressly allow research facilities to conduct genetic testing and use genetic information for scientific research purposes so long as the identity of any individual tested is not disclosed to a third party without the individual's consent.<sup>110</sup>

#### 5. Louisiana

Louisiana law provides that "[a]n insured's or enrollee's genetic information is the property of" that person and that no person may retain that information without consent.<sup>111</sup> The law provides exceptions for the purposes of criminal investigation proceedings and determining paternity.<sup>112</sup> This statute also proscribes certain conduct by insurance companies, such as denying coverage to an individual or family member on the basis of any genetic information concerning either of those persons.<sup>113</sup> The focus on insurance coverage, as well as the statute's location within Louisiana's insurance code, suggests that the scope of the property right to genetic information may be confined only to insurance coverage.<sup>114</sup>

#### *B. The Language of Proposed State Genetic Property Rights*

The genetic property laws discussed above have set the stage for lawmakers who wish to provide their constituents with a meaningful right

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107. *Id.* at 1075.

108. GA. CODE ANN. § 33-54-1(1) (2005).

109. *Id.* § 33-54-1(4).

110. *Id.* § 33-54-6.

111. LA. REV. STAT. ANN. § 22:1023(E) (Supp. 2013).

112. *Id.* § 22:1023(E)(1)–(2).

113. *Id.* § 22:1023(B)(1)(c).

114. See Jana M. Belflower, Note, *Keeping Pace with Progress: A Proposal for Florida's Genetic Testing Statute*, 42 STETSON L. REV. 249, 264–65 (2012) (suggesting that Louisiana's statute provides minimal protections to genetic information, as the statute only applies in the context of health insurance).

to their genetic information. To determine whether the proposed laws in Massachusetts, South Dakota, and Vermont would fulfill that purpose, we must look first to their plain language.<sup>115</sup>

### 1. Massachusetts's Genetic Bill of Rights

Massachusetts's Genetic Bill of Rights (GBR) recognizes that genetic information "is a unique product of an individual's body" and that the unauthorized use of this information interferes with the individual's privacy rights and property interests.<sup>116</sup> One of the GBR's expressly stated goals is to "declare genetic information the exclusive property of the individual from whom the information is obtained."<sup>117</sup> This legislation goes much further than existing genetic information laws, providing that

[g]enetic material shall be considered real property subject to one's individual control and dominion in accord with *generally held precepts of property law in the Commonwealth . . .* In the case where an entity collects genetic material or genetic information with the possible future intent of resale, licensing, or transfer of this material for collateral gain, the individual who provided the genetic material or information must be made aware and compensated at a *fair market value.*; [sic] *Prior to entering into a contract to share one's personal health information, genetic material or genetic information, a person must be made aware both orally and in writing that their donation is a commodity and is of some material value.*<sup>118</sup>

Thus, Massachusetts's GBR goes to great lengths to avoid the ambiguity that has limited genetic property rights in other jurisdictions.<sup>119</sup> Unlike Florida's genetic information law, for example, the GBR explicitly incorporates common law property rights.<sup>120</sup>

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115. See *United States v. Turkette*, 452 U.S. 576, 580 (1981) ("In determining the scope of a statute, we look first to its language.").

116. S. 1080, 187th Gen. Court, Reg. Sess. § 1 (Mass 2011), available at <http://malegislature.gov/Bills/187/Senate/S1080>.

117. *Id.*

118. *Id.* (emphasis added). The designation of genetic material as "real property" is somewhat odd because that term normally concerns land and property attached to it. See, e.g., BLACK'S LAW DICTIONARY 1379 (9th ed. 2009) (defining "real things" as "[p]roperty that is fixed and immovable, such as lands and buildings; real property").

119. See *supra* Parts III.A.1, III.A.3.

120. Compare S. 1080, § 1, with FLA. STAT. ANN. § 760.40(2)(a) (West 2010).

The Massachusetts GBR was filed on January 21, 2011, and was heard in the Joint Committee on Public Health on March 28 of the same year.<sup>121</sup> On September 20, 2012, the Massachusetts Senate considered an order directing the Joint Committee to investigate and study this Bill, along with many others relating to environmental health, physical health, health-related research, etc.<sup>122</sup> The order was discharged to the Senate Committee on Ethics and Rules four days later.<sup>123</sup> The Senate has taken no other action on the GBR.<sup>124</sup>

## 2. South Dakota's Genetic Information Bill

South Dakota's ill-fated genetic information bill, H.B. 1260, provided that “[a]ll DNA, genetic information, or results of any genetic test, as related to health benefit plans, are the sole property of the person from whom it was derived.”<sup>125</sup> Like its counterparts in Colorado, Georgia, and Louisiana, this legislation apparently would have granted a property right narrowly defined for insurance purposes. The bill was first read in the South Dakota House of Representatives on January 26, 2012, and was “[d]eferred to the 41st legislative day” on February 2, 2012.<sup>126</sup> This procedural step effectively killed the bill.<sup>127</sup>

## 3. Vermont's Genetic Information Bill

Vermont's genetic information bill, H. 368, is substantially similar to Massachusetts's GBR. Like the GBR, H. 368 declares that “genetic information is a unique product of an individual's body” and is “the exclusive property of the individual from whom the information is obtained.”<sup>128</sup> H. 368 also provides that genetic material is “real” property that has material value, and it establishes criminal penalties for

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121. *Bill S.1080*, MASS. LEGISLATURE, <http://www.malegislature.gov/Bills/187/Senate/S01080/History> (last visited Oct. 21, 2013) [hereinafter *Bill S.1080*].

122. *Bill S.2438*, MASS. LEGISLATURE, <http://www.malegislature.gov/Bills/187/Senate/S02438/History> (last visited Nov. 7, 2013).

123. *Id.* (noting that the order was discharged to the Ethics Committee on September 24, 2013).

124. *Bill S.1080*, *supra* note 121.

125. H.B. 1260, 2012 Legis. Assemb., 87th Sess. § 2 (S.D. 2012), available at <http://legis.state.sd.us/sessions/2012/Bills/HB1260P.pdf>.

126. 2012 Session—*Bill History: House Bill 1260*, S.D. LEGISLATURE, <http://legis.state.sd.us/sessions/2012/QuickFind.aspx> (search “1260” in the query field) (last visited Nov. 7, 2013).

127. *How an Idea Becomes Law*, S.D. LEGISLATURE, <http://legis.state.sd.us/students/idealaw.pdf> (last visited Nov. 7, 2013).

128. H. 368, 2011–2012 Leg., Reg. Sess. § 1 (Vt. 2011), available at <http://www.leg.state.vt.us/docs/2012/bills/Intro/H-368.pdf>.

misappropriation of genetic material.<sup>129</sup> The bill goes even further than the GBR, however, stating that information derived from “the sequence of the human genome” is part of the public domain and is not the property of any individual.<sup>130</sup> This provision appears to be a direct attack on the patentability of DNA and would likely have been unconstitutional if the Supreme Court had upheld the patentability of isolated DNA.<sup>131</sup> H. 368 was referred to the Vermont House Committee on Human Services on March 8, 2011.<sup>132</sup> The legislature has taken no further action on it.<sup>133</sup>

### C. What Would These Proposed Laws Actually Do?

Public reactions to these legislative efforts have been mixed.<sup>134</sup> Some commentators have taken issue with identifying genetic *material* as property.<sup>135</sup> One problem with this proposed property right is that genetic material sheds quite easily and may quickly become discarded or abandoned property.<sup>136</sup> Thus, it is unclear how a state could enforce an individual’s exclusive right to this material. Other commentators have expressed concern that this legislation could impede innovative genetic research and limit educational use of genetic data.<sup>137</sup> Furthermore, this legislation may be premature because we are still exploring the human genome and the role of genomics in human health and the quality of life.<sup>138</sup>

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129. *Id.* §§ 4, 14.

130. *Id.* § 4.

131. See U.S. CONST. art. VI, cl. 2 (“[T]he Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”); see also Dan Vorhaus, *Is the Genetic Rights Movement Picking up Steam?*, GENOMICS L. REP. (Mar. 16, 2011), <http://www.genomicslawreport.com/index.php/2011/03/16/is-the-genetic-rights-movement-picking-up-steam/> (suggesting that this provision is a “way of asserting . . . support for the plaintiffs in the ongoing *Myriad* gene patent litigation by asserting . . . that none of the Human Genome Project’s fruits shall be patentable”).

132. *The Vermont Legislative Bill Tracking System: H. 368*, VT. STATE LEGISLATURE, <http://www.leg.state.vt.us/database/status/summary.cfm?Bill=H.0368&Session=2012> (last visited Nov. 7, 2013).

133. *Id.* (listing no updates after the referral).

134. See, e.g., Mike Masnick, *Do You Have Property Rights Over Your DNA?*, TECHDIRT (July 27, 2011, 10:48 AM), <http://www.techdirt.com/articles/20110725/16530815246/do-you-have-property-rights-over-your-dna.shtml> (expressing ambivalence with respect to these proposals); Vorhaus, *supra* note 131 (recognizing that Vermont’s bill would have both good and bad implications if passed).

135. E.g., Masnick, *supra* note 134.

136. *Id.*

137. E.g., Susan Huber & Dan Vorhaus, *Genetic Bill of Rights Proposed in Massachusetts*, GENOMICS L. REP. (Feb. 14, 2011), <http://www.genomicslawreport.com/index.php/2011/02/14/genetic-bill-of-rights-proposed-in-massachusetts/>.

138. *Id.*



Lastly, commentators have noted that it is unclear how to determine the fair market value of genetic information.<sup>139</sup>

On the other hand, these proposals—with the exception of South Dakota's H.B. 1260—are substantially more protective than existing genetic property laws. Unlike their counterparts in Colorado, Georgia, and Louisiana, Massachusetts's GBR and Vermont's H. 368 extend beyond insurance coverage. Both laws explicitly provide that genetic information is a commodity of "some material value."<sup>140</sup> Furthermore, in an apparent attempt to avoid the fatal ambiguity in Florida's (and possibly Alaska's) genetic information law, both bills explicitly provide that genetic information is subject to "generally held precepts of property law."<sup>141</sup> In other words, the bills would seem to empower individuals to bring common law causes of action, such as conversion,<sup>142</sup> against individuals who infringe this property right.

From a legal perspective, it is hard to predict exactly what a property interest in genetic information would entail. The traditional bundle of rights encompassed by property ownership includes the right to exclude, the right to transfer, and the right to use.<sup>143</sup> What does this mean in the context of genetic property rights? The right to transfer genetic information seems, at first glance, rather straightforward. An individual who possesses property rights over his or her personal DNA necessarily has the right to sell that information. However, as demonstrated below,<sup>144</sup> this right is complicated by the fact that little genetic differentiation exists between individuals. Thus, it is hard to conceptualize an exclusive right to sell information that many, if not all, individuals already possess. More importantly, at least to those who hope to profit from the sale of their genetic information, who is willing to pay for that information? For this same reason, the right to exclude others from genetic information is also counterintuitive. Because this information is largely universal, no one has exclusive access to it. Thus, in practical effect, the right to exclude others from one's own genetic information is necessarily limited to the sum total of those few genetic differences that define us as individuals.<sup>145</sup>

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139. *Id.*

140. S. 1080, 187th Gen. Court, Reg. Sess. § 2(b) (Mass 2011), available at <http://malegislature.gov/Bills/187/Senate/S1080>; H. 368, 2011–2012 Leg., Reg. Sess. § 4 (Vt. 2011), available at <http://www.leg.state.vt.us/docs/2012/bills/Intro/H-368.pdf>.

141. S. 1080, § 2(b); H. 368, § 4.

142. See 1 RAYMOND T. NIMMER, INFORMATION LAW § 2:28 (2006) (noting that some courts have extended the tort of conversion to cover intangible property).

143. JOHN G. SPRANKLING, UNDERSTANDING PROPERTY LAW § 1.03[B][1] (2000).

144. See *infra* Part V.A.

145. This is a bit problematic for identical twins.

The right to use genetic information is perhaps the most controversial. What does it mean to “use” this information? Aside from its biological role in protein synthesis, genetic information provides us with valuable insight into our identities and maybe even our future.<sup>146</sup> The exclusive right to use genetic information necessarily includes the right to *study it*. This information is unintelligible until we sequence and analyze it. However, as explained more fully below,<sup>147</sup> some sequencing technologies could have infringed isolated DNA patents. Thus, had the Supreme Court upheld isolated DNA patents, the right to sequence DNA would have existed at the mercy of patentees. Testing for the presence of certain genetic mutations would have been especially hazardous because this process was much more likely to infringe isolated DNA patents.<sup>148</sup> Thus, the right to use DNA would have come with a rather alarming disclaimer: MAY CONSTITUTE PATENT INFRINGEMENT.

These difficulties in conceptualizing property rights to DNA may explain why states would go to great lengths to protect many of our personally identifying features<sup>149</sup> but not the genetic blueprint upon which they are based. But difficulty does not justify inaction. The few genetic differences that exist between one person and the next are no less important to our identity than our likeness or voice. Moreover, now that the Supreme Court has invalidated isolated DNA patents, states like Vermont and Massachusetts are free to define genetic information as personal property without fear that those rights would be effectively preempted by federal intellectual property rights. The time is now ripe for lawmakers to provide at least *some* control over what is perhaps the most important component of a person’s identity.

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146. Amy Harmon, *Seeking Ancestry in DNA Ties Uncovered by Tests*, N.Y. TIMES, Apr. 12, 2006, [http://www.nytimes.com/2006/04/12/us/12genes.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2006/04/12/us/12genes.html?pagewanted=all&_r=0) (exploring the use of DNA testing in determining ancestry).

147. See *infra* Part IV.B.

148. See, e.g., Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 187–89 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom.* Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (noting that the patents-in-suit prevented several doctors from sharing genetic testing results with patients).

149. See CAL. CIV. CODE § 3344(a) (West 2007) (prohibiting use of identifying features without owner’s consent); OKLA. STAT. ANN. tit. 12, § 1449(A) (West 2010) (same); N.Y. CIV. RIGHTS LAW § 51 (McKinney 2009) (barring use of identifying features in advertisement without owner’s consent); RESTATEMENT (SECOND) OF TORTS § 652C (1977) (identifying tort action against those using identifying features without owner’s consent).

#### IV. THE INTERACTION BETWEEN INTELLECTUAL AND PERSONAL PROPERTY RIGHTS

As noted in Part III, until the Supreme Court invalidated isolated DNA patents, federal patent law posed a significant hurdle for legislative efforts to define genetic material and information as personal property. To understand how these patent rights would have interacted with personal property rights—and to see why invalidating isolated DNA patents was a victory for personal property rights—it is necessary to first explore the scope of patent protection.

##### *A. What Rights Do Patents Confer?*

Patents consist of specifications and claims.<sup>150</sup> The specifications describe the invention, the components, how the components work, and how the components work together to perform a specified function.<sup>151</sup> Claims establish the boundary of the property right, much like the “metes and bounds” of a real estate deed.<sup>152</sup> Interpreting claims is notoriously difficult, and even the courts frequently disagree on the proper interpretation of a particular claim.<sup>153</sup>

The patentee’s rights over the claimed invention are rather expansive. The patent holder has the right to exclude others from making, using, selling, offering for sale, or importing the claimed invention for twenty years, beginning on the date the patent application is filed.<sup>154</sup>

##### *B. Would Isolated DNA Patents Limit Personal Property Rights to DNA?*

DNA patents are particularly difficult to interpret, especially because they are rarely litigated.<sup>155</sup> Under the Federal Circuit’s broad and evidently erroneous interpretation of isolated DNA patents in *Molecular Pathology*, covalent bonds could serve as the “defining boundary” between patentable

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150. MERGES ET AL., *supra* note 53, at 129.

151. *Id.*

152. *Id.* (internal quotation marks omitted).

153. Christopher M. Holman, *Will Gene Patents Impede Whole Genome Sequencing?: Deconstructing the Myth that 20% of the Human Genome is Patented*, 2 IP THEORY 1, 3 (2012), available at <http://www.repository.law.indiana.edu/ipt/vol2/iss1/1> (observing that the Federal Circuit often reverses the trial courts’ interpretations and that disagreement among Federal Circuit judges is not “uncommon”).

154. MERGES ET AL., *supra* note 53, at 130; U.S. Patent Act, 35 U.S.C. §§ 154(a)(1)–(2), 271(a) (2006).

155. Holman, *supra* note 153, at 3–4.

DNA and naturally occurring DNA.<sup>156</sup> In other words, a valid claim to isolated DNA would need only to define molecules that have been “chemically cleaved from their native chemical combination with other genetic materials.”<sup>157</sup> Thus, before *Myriad*, the only difference between patented DNA and naturally occurring DNA was the length of the molecule. The isolated DNA would still be patentable even if it were chemically identical to a portion of the naturally occurring DNA molecule.

At first blush, isolated DNA patents would not appear to pose a serious risk of limiting the personal property right to DNA. To infringe this type of patent, an individual would need to create a molecule containing only the claimed sequence or sequences of DNA.<sup>158</sup> This molecule does not exist in nature, and therefore no one would infringe the patent by merely existing.<sup>159</sup> Nor would anyone infringe the patent by selling their genetic material. Although the claimed sequence of DNA would be contained in an individual’s genome, the molecule that person sells would be chemically distinct from any patented DNA molecule.

A much greater concern was that the mere act of sequencing a person’s genome would infringe the patent.<sup>160</sup> Outside of its biological functionality, DNA is only useful if it can be sequenced.<sup>161</sup> A person’s genome contains valuable information about his or her identity; indeed, genetic tests “are reshaping people’s sense of themselves—where they came from, why they behave as they do, what disease might be coming their way.”<sup>162</sup> Therefore, the right to sequence one’s own DNA would seem to be inseparable and crucial to its definition as personal property.

Some scholars have concluded that isolated DNA patents would not hinder any right to sequence personal DNA.<sup>163</sup> However, at least some

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156. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1329 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

157. *Id.*

158. In some cases, a 100% match between the patented sequence and the allegedly infringing sequence is not required; thus, some claims to isolated DNA cover many unique but very similar sequences. W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won’t Hinder Whole Genome Sequencing and Personalized Medicine*, 33 *CARDOZO L. REV.* 1601, 1610 (2012).

159. Although this concern may seem whimsical, it was significant enough to receive a formal response from the PTO. Utility Examination Guidelines, 66 *Fed. Reg.* 1092, 1093 (Jan. 5, 2001) (“Another comment expressed concern that a person whose body includes a patented gene could be guilty of patent infringement.”).

160. Holman, *supra* note 153, at 1.

161. See Andrew Bowman, Note, *Genes 101: Are Human Genes Patentable Subject Matter?*, 18 *RICH. J.L. & TECH.* 15, 20 (2012) (stressing the value of genetic information to organisms).

162. Harmon, *supra* note 146.

163. E.g., Holman, *supra* note 153, at 2 (“[M]y analysis of the claims in a large sampling of . . . patents identified . . . as ‘gene patents’ indicates that the fear that gene patents will impede [whole

concede that traditional “shotgun” sequencing *could* infringe certain DNA patents.<sup>164</sup> Shotgun sequencing occurs in several steps: first, naturally occurring DNA is isolated from its native environment; second, this DNA is broken down into fragments generally ranging from twenty-five to 1,000 nucleotides; third, the fragments are sequenced; and, finally, the fragment sequences are assembled into the whole genome.<sup>165</sup> The specter of infringement arises during fragmentation. Because this process is random, it is possible to generate fragments that are identical or sufficiently similar to a patented sequence.<sup>166</sup> However, this fragmentation step would not infringe many isolated DNA patents because most genes are much longer than 1,000 nucleotides.<sup>167</sup> Thus, even if a fragment were chemically identical to a portion of a patented gene, it would not be identical to, or sufficiently similar to, the claimed molecule itself and would therefore be non-infringing.

The problem was that a substantial number of (now invalid) patents claimed very small portions of genes.<sup>168</sup> For example, one patent claimed a DNA molecule consisting of only ten contiguous nucleotides located within an isolated gene.<sup>169</sup> Although the validity of such patents was suspect even before *Myriad*,<sup>170</sup> the threat of litigation alone could have been sufficient to deter lawful sequencing activities. Moreover, it is difficult to determine where or how a court would have drawn the line between patent-eligible DNA molecules and those that were too short to meet the requirements of patentability. Using the Federal Circuit’s reasoning in *Molecular Pathology*, any DNA molecule that does not exist in nature and meets all the other requirements for patentability<sup>171</sup> would be patentable subject matter. The requirements for patentability are not trivial, and most small fragments of DNA probably would fail to meet at least one of the requirements. However, it is conceivable that a clever inventor—aided by

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genome sequencing] has, in all likelihood, been greatly overstated.”); Price II, *supra* note 158, at 1606 (concluding that “most, if not all isolated DNA gene patents are likely not infringed by [whole genome sequencing]”).

164. *E.g.*, Price II, *supra* note 158, at 1623 (“Overall, it appears that the two traditional [whole genome sequencing] techniques are likely to infringe a small number of whole-gene claims and a much larger number of potentially invalid short-sequence claims.”).

165. *Id.* at 1620.

166. *Id.* at 1619, 1621–22.

167. *Id.* at 1622; Holman, *supra* note 153, at 9.

168. Holman, *supra* note 153, at 9.

169. *Id.* (citing U.S. Patent No. 5,559,023 (filed Feb. 7, 1995)).

170. *Id.* at 9–10. One reason for invalidating such claims is that they cover “much more than the inventor actually invented.” *Id.* at 10.

171. The five requirements for a valid patent are: (1) patentable subject matter, (2) utility, (3) novelty, (4) nonobviousness, and (5) enablement (i.e., explained in a way that enables others to make and use the invention). MERGES ET AL., *supra* note 53, at 128.

an equally clever patent attorney—could have isolated a sequence of DNA that was sufficiently long to meet the requirements of patentability and yet short enough to be infringed during shotgun sequencing.

As of 2011, no one had ever been sued for patent infringement based on the sequencing of an individual's genome.<sup>172</sup> This may be due to the presumed difficulty of identifying and proving infringement—the patent holder must have access to the fragment sequences—and the possibility of a retaliatory response from other patent holders who have claimed small segments of DNA.

Advances in sequencing technology likely would have eliminated the risk of infringement during whole genome sequencing. For example, nanopore sequencing does not include the fragmentation step; rather, it is designed to read long strands of DNA sequentially, one nucleotide at a time.<sup>173</sup> At no point would it be necessary to break DNA into gene-sized or smaller fragments. However, this technology is not commercially available,<sup>174</sup> and thus the specter of litigation from shotgun sequencing would haunt genetic property rights for at least a few more years.

Practically speaking, though, nothing would have stopped anyone from sequencing his or her DNA. Those who have staked claims to small sequences of DNA have decided not to bring legal action against anyone who uses shotgun sequencing technology. Thus, in practice, federal patent law would not hinder an individual's right to sequence his or her DNA. From a legal perspective, however, there would have been some tension between the federal property right to isolated DNA and the personal property right to DNA.

## V. THE INFORMATIONAL RIGHTS CONFERRED BY ISOLATED DNA PATENTS

The chemical-based approach described in the preceding Part does not tell the whole story. As one scholar observed, “[t]he chemical perspective ignores the significance of the information content of DNA and, specifically, a gene.”<sup>175</sup> The Supreme Court agreed that the real value of Myriad's isolated DNA patents derived from the exclusive right to information, not the chemical composition of the DNA molecules.<sup>176</sup> Thus,

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172. Holman, *supra* note 153, at 1.

173. Price II, *supra* note 158, at 1624–25.

174. *Id.* at 1624.

175. Bowman, *supra* note 161, at 18.

176. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2118 (2013). The Court observed that

[i]f [Myriad's isolated DNA] patents depended upon the creation of a unique

isolated DNA patents would have significantly limited the right of individuals to utilize and study their own genetic information. On the other hand, granting researchers lucrative rights to isolated DNA would have given monetary value to an individual's DNA. Thus, the very same property scheme that would have constricted the right to personal genetic information also could have made it more financially rewarding.

*A. The Drawback: Limiting Access to One's Own Genetic Information*

Much of the human genome is shared. In fact, the amount of genetic variation between two humans is, on average, about 0.1%.<sup>177</sup> In other words, only one nucleotide pair out of 1,000 will differ between any two individuals.<sup>178</sup> This near-universality of the human genome allows inventors to stake claims to portions of DNA that exist in every individual. Thus, isolated DNA patents conferred more than just the right to produce a chemical compound; they granted the patent holder the exclusive right to study the *information* stored in many, if not all, humans. This was particularly troubling because DNA, unlike many other patented "inventions," is not a product that an individual must purchase before he or she can claim personal property rights over it. Every human is born with DNA, and from the moment of birth, each individual was precluded from accessing information stored in his or her own body. Fundamental rights aside, this would have constituted a significant limitation of any personal property right to human DNA. As noted above,<sup>179</sup> the right to own DNA necessarily includes the right to use the information it contains. By allowing third parties to stake claims to genetic real estate, the PTO was effectively imposing servitudes on property that the patent holders never created.

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molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes . . . by isolating a DNA sequence that included both the [patented] gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule.

*Id.* (emphasis in original).

177. *Teacher's Guide: Understanding Human Genetic Variation*, NAT'L HUMAN GENOME RESEARCH INST., NAT'L INST. OF HEALTH, [http://science.education.nih.gov/supplements/nih1/genetic/guide/genetic\\_variation1.htm](http://science.education.nih.gov/supplements/nih1/genetic/guide/genetic_variation1.htm) (last visited Nov. 7, 2013).

178. *Id.*

179. See *supra* Part III.C.

*B. The Flip Side: The Right to Sell DNA*

Isolated DNA patents were quite lucrative.<sup>180</sup> By granting researchers exclusive rights over genetic information, the federal government created a powerful incentive to explore unclaimed territory on the genetic frontier. If state efforts to define genetic information as personal property had succeeded, and if the Supreme Court had upheld isolated DNA patents, then individuals would have had an opportunity to financially benefit from the patenting of human DNA. In particular, by defining an individual's DNA as a commodity of some material value—as Massachusetts and Vermont are proposing<sup>181</sup>—states could have given individuals bargaining power over the use of their genetic information in research that eventually would have resulted in the patenting of isolated DNA.

In effect, states could have countered the harm of isolated DNA patents by establishing a sequential division of genetic property rights. An unpatented sequence of DNA would have initially belonged to the individuals who harbored it. If researchers were interested in studying a particular sequence, they would have needed to first purchase the right to do so from someone who possessed it.<sup>182</sup> The exclusive right to DNA would have shifted to the researchers only after they had purchased the right to study the sequence and patented the sequence. Ultimately, this would have been the *only* option states had to combat the apparent inequity in allowing researchers to stake claims over the human genome. Because patent law is exclusively the domain of the federal government,<sup>183</sup> state legislators had only little authority to protect their constituents' interest in their own genetic information. By giving monetary value to personal DNA, states would have given individuals a financial stake in the patenting of human DNA.

Now that the Supreme Court has invalidated isolated DNA patents, lawmakers can offer their constituents meaningful property rights to their DNA—rights that may be exerted freely and without the permission of

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180. See Andrew Pollack, *Despite Gene Patent Victory, Myriad Genetics Faces Challenges*, N.Y. TIMES, Aug. 24, 2011, [http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?pagewanted=all&_r=0) (describing Myriad's DNA patents as "lucrative").

181. S. 1080, 187th Gen. Court, Reg. Sess. § 2(b) (Mass 2011), available at <http://malegislature.gov/Bills/187/Senate/S1080>; H. 368, 2011–2012 Leg., Reg. Sess. § 4 (Vt. 2011), available at <http://www.leg.state.vt.us/docs/2012/bills/Intro/H-368.pdf>.

182. However, as observed *supra*, Part III.C, the right to *exclude* others from genetic information should only extend to the sum total of the unique genetic differences between one person and the next. Thus, one individual may not stop another from selling a sequence that both share.

183. U.S. CONST. art. I, § 8, cl. 8, art. VI, cl. 2.



those who claimed ownership of the human genome. Moreover, because other types of DNA patents remain valid,<sup>184</sup> and because the medical, academic, and industrial value of genetic information will likely continue to spur research into the human genome, individuals still may have an opportunity to profit from the use of their genetic information in research. Of course, as noted above,<sup>185</sup> critics of these proposed property rights are wary of burdening innovation with the costs of bartering for human DNA. But it is difficult to estimate this financial burden. As suggested earlier, no one should have the exclusive right to information that is shared, and because much of our genetic information *is* shared, nothing would stop researchers from seeking out the least-demanding sellers or even asking individuals to donate their genetic information. On the other hand, individuals who knowingly harbor rare genetic traits would be in a superior bargaining position, and the price of their genetic information could be significantly higher. Ultimately, lawmakers would have to decide which limits, if any, they should place on the sale of human DNA.

It is important to recognize, though, that personal property rights to human DNA would serve a higher purpose than merely shifting some of the financial rewards of biotech research to the sources of the genetic information on which the research was based; for most donors of genetic information, the financial rewards would be insignificant.<sup>186</sup> The true value of this property right is its empowerment of individuals to determine—through contractual arrangements—the fate of their genetic information and the purposes for which it is used.

#### CONCLUSION

The Supreme Court's recent invalidation of isolated DNA patents has opened the door for lawmakers to define DNA as personal property. Though this personal property right would have been distinct from the now-invalid property rights conferred by isolated DNA patents, the two property schemes would have been largely incompatible. Because some patent

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184. As noted *supra*, note 52, cDNA patents remain valid. See also Adrian Tombling, *Ban on Human Gene Patents is Baffling But It Won't Impede Biotech Research*, THE GUARDIAN (June 18, 2013, 8:51 AM), <http://www.guardian.co.uk/science/blog/2013/jun/18/ban-human-gene-patents-biotech-research> (“Most patent applications for biotech innovations include a variety of different claims and are very unlikely to rely on a claim directed to just the naturally occurring gene sequence.”).

185. See *supra* note 137 and accompanying text.

186. Cf. Audrey Quinn, *What Rights Should You Have to Your Own DNA?*, SMARTPLANET (May 21, 2012, 3:54 PM), <http://www.smartplanet.com/blog/rethinking-healthcare/what-rights-should-you-have-to-your-own-dna/8872> (suggesting personal property rights to one's DNA are a mechanism to protecting personal privacy); Masnick, *supra* note 134 (“Realistically speaking, this is a privacy issue, but it's being framed by some as a ‘property rights’ issue . . .”).

holders had a legal right to sue anyone who—even unintentionally—produced their claimed sequence during whole genome sequencing, DNA patents theoretically imposed a barrier to genetic sequencing. This barrier would have significantly limited the personal property right to DNA because the right to use one's own DNA necessarily entails the right to sequence it. Furthermore, isolated DNA patents conferred an exclusive right to study information that is stored in many, if not all, humans. Thus, a patent holder could have prevented individuals from analyzing information within their own genome. This would have imposed a severe limitation on any personal property right to human DNA.

But the invalidation of isolated DNA patents was only one step in the path to providing a meaningful personal property right to DNA. Lawmakers must now consider the contours of this right—for example, should the property right extend to genetic material despite its frequent abandonment?—and, more importantly, its effects on biotech research and medicine. This will be a contentious issue and will require input from various stakeholders, including the biotech industry, medical practitioners, and civil rights groups. With time and, hopefully, an appreciation of the importance of DNA to human identity, lawmakers may be able to reach a satisfactory—or at least tolerable—result for all interested parties.

Though certainly flawed, the recent legislative efforts to define DNA as personal property are laudable attempts to correct a rather glaring inconsistency in personal property law. By defining DNA as personal property, lawmakers would enable individuals to profit from the use of their genetic information. The true value of this property scheme, however, would derive not from the monetization of human genetic information but rather from the empowerment of individuals to control the fate of one of the most fundamental components of their identity—their unique sequence of nucleotides.

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