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Joann A. Boughman, PhD* Kyle M. Brown, PhD**

The Geneticists' Approach to *Bilski*

THE PATENT PROCESS AND ITS ASSOCIATED CASE LAW HAVE become increasing familiar to genetic research scientists and medical geneticists.[1] For example, nearly 1% (19 of 3100) of researchers who applied to present research at the 2011 annual meeting of the American Society for Human Genetics reported a possible or perceived financial conflict of interest based on their intellectual property holdings.[2] Guided by the interests of their members, professional organizations of geneticists, like the American Society of Human Genetics (ASHG) and others, have become responsive to and involved in the legal processes involved with intellectual property protection.[3] In *Bilski v.*

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1. *See generally* Alex Osterlind, *Staking a Claim on the Building Blocks of Life: Human Genetic Material within the United States Patent System*, 75 MO. L. REV. 617 (2010) (discussing the patentability of genetic material); D. Benjamin Borson, *The Human Genome Projects: Patenting Human Genes and Biotechnology. Is the Human Genome Patentable?*, 35 IDEA 461, 461 (1995) (analyzing the legal issues surrounding patent protection of the products of studies of the human genome). For additional information on genetic patents, *see* DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 50–55 (2004).

2. American Society of Human Genetics, 60th Annual Meeting Program, 361–63 (2010), http://www.ashg.org/2010meeting/pdf/ASHG_program.pdf.

3. *See, e.g.*, Brief for American Society of Human Genetics et al. as Amici Curiae Supporting Plaintiffs' Opposition to Defendants' Motion To Dismiss and Supporting Plaintiffs' Motion for Summary Judgment at 6, Ass'n for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al., 702 F.Supp.2d 181 (2009) (No. 09 Civ. 4515), 2009 WL 3269106 (S.D.N.Y.); Brief for The American College of Medical Genetics, et al. as Amici Curiae Supporting Respondents at 1, Bilski v. Kappos, 130 S. Ct. 3218 (2010).

Kappos,[4] the Supreme Court ruled on the patentability of certain subject matter for the first time in 30 years.[5] The ruling has potential implications for a variety of patentable "arts," including medical and research genetics, but the narrow scope of this ruling, in conjunction with other decisions, has left significant uncertainty in the field of human genetics about what constitutes patentable material.[6]

In order to continue producing innovative research and discoveries that will contribute to the treatment of disease, genetics researchers need more legal certainty about the patentability of genetic methods and materials.[7] By applying a current understanding of medical and research genetics to questions of patentability, courts will be able to resolve ambiguities in patent jurisprudence while stimulating innovation and access to the benefits of genetically informed medicine.[8]

The genetics community has taken a balanced approach, embracing the protection of intellectual property while fostering openness in research.[9] However, recent court decisions and patent office precedents defy the original intent of the patent process by allowing genetic patents that may be

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4. 130 S. Ct. 3218 (2010).

5. *See* Diamond v. Diehr, 450 U.S. 175 (1981) (holding that process claims for curing rubber were patentable despite including the use of a known equation); Parker v. Flook, 437 U.S. 584 (1978) (noting that method claims containing algorithms are not patentable)*; see also* MJ Edwards & Donald Steinberg, *The Implications of* Bilski: *Patentable Subject Matter in the United States*, 49 IDEA 411, 413 (2009) (noting that "the line between what is patentable and what is not is not always clear. The Supreme Court addressed this line in a series of decisions that are now more than twenty-five years old . . ."). *Id.*

6. *See* Chris Holman, *The Impact of* Bilski *on Biotechnology*, HOLMAN'S BIOTECH IP BLOG (July 3, 2010, 11:22 AM), http://holmansbiotechipblog.blogspot.com ("[T]he Supreme Court provided little if any guidance with respect to what it means for a patent to claim a fundamental principle, and absolutely no guidance with respect to how to apply the test when the fundamental principle is a biological natural phenomenon . . . .").

7. *See* Jennifer Giordano-Coltart et al., *No Legal Monopoly for Genes: Court Rules Genes are Unpatentable Subject Matter*, INTELL. PROP. & TECH. L.J. 8, 12 (2010) (discussing the uncertainties presented by Supreme Court's ruling and its chilling effect on genetic research and innovation in the medical field).

8. *See* Holman, *supra* note 6 (suggesting that the Court should draw a line between biological phenomena that occur absent human intervention and phenomena that occur as a result of human intervention when determining what constitutes patentable subject matter in the genetic context).

9. *See* Matthew Herper, *Genome Scientists: Gene Patents are Bad*, FORBES (June 26, 2002), http://www forbes.com/2002/06/26/0626targets html (discussing the balance between gene patents and accessibility of information). For additional information and an overview of the arguments for and against gene patenting, *see generally* HUMAN GENOME PROJECT INFORMATION*, Genetics and Patenting*, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml. (last modified July 7, 2010).

detrimental to innovation and discovery.[10] The courts should protect intellectual property while recognizing the patent ineligibility of genetic principles and naturally occurring gene sequences.

I. BASIC GENETIC METHODOLOGIES

As with many applications, the eligibility of specific discoveries and inventions in the field of genetics hinge on a detailed understanding of the technical details underlying the application.[11] By understanding fundamentals of genetics methodologies, the courts can better understand whether an application represents a "new and useful process, machine, manufacture or composition of matter."[12]

Often described as a double helix, DNA can be conceptualized as a twisted zipper that can be opened and closed.[13] In this analogy, individual chemicals make up the teeth of the DNA zipper.[14] When closed, the zipper is held together by forces similar to static electricity.[15]

Unlike zippers on your clothing, the teeth of DNA zippers come in four different types.[16] Symbolized by the letters A, C, T and G, the

10. *See* Joseph Stiglitz & John Sulston, *The Case Against Gene Patents*, WALL ST. J., Apr. 16, 2010, at A19 (stating that genetic patents inhibit access to basic information and may impede scientific progress); *see also* RESNIK, *supra* note 1, at 202 (stating that "[p]atents on biological materials, such as DNA, provide crucial incentives for this developing industry, but they also threaten the progress of science, the practice of medicine, the development of agriculture, and the preservation of cultural notions concerning the value of human life[]"); *see Intellectual Property Rights Must be Balanced with Research Needs to Realize Full Potential of Biomedical Research*, OFFICE OF NEWS AND PUB. INFO. (Nov. 17, 2005), http:// www8 nationalacademies.org/ onpinews/newsitem.aspx?RecordID=11487 (emphasizing the need for balance between protecting research discoveries and granting access to these discoveries by awarding gene patents to some, but not all genomic material).

11. *See* RESNIK, *supra* note 1, at 40 (noting that in DNA patenting courts require a detailed and precise description of the DNA sequence to be patented (citing Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997))).

12. 35 U.S.C. § 101 (2006); *see generally* Stiglitz & Sulston, *supra* note 10 (discussing the complex nature of gene patents and how the Court's future decisions should be based upon this nature).

13. *See* ALVIN SILVERSTEIN ET AL., DNA 18 (2002) (describing DNA as a zipper); DANIEL L. HARTL & ELIZABETH W. JONES, ESSENTIAL GENETICS: A GENOMICS PERSPECTIVE 7 (Lianne Ames ed., 3d ed. 2002) (identifying the subunits of DNA as chemical constituents known as bases).

14. HARTL & JONES, *supra* note 13, at 7.

15. The chemical components of DNA are partnered together by hydrogen bonds, where hydrogen atoms on one strand are attracted to electronegative oxygen or nitrogen atoms on the other. *See* HARTL & JONES, *supra* note 13, at 215.

16. *See id.* (describing the four bases in DNA as Adenine, Guanine, Thymine and Cytosine).

presence of one type of "tooth" on one side of the "zipper" (e.g. an "A"), dictates the identity of the tooth on the other side (in this case, a "T").[17] In this way, the sequence of teeth on one side of the zipper — the DNA helix —determines the sequence on the other side.[18] Every time a human cell divides, it "unzips" its DNA in order to create two exact replicas of its genes, known as its genome.[19]

Research and diagnostic techniques take advantage of the zipper-like qualities of DNA in order to read the sequence of A's, T's, C's and G's that make up human genes and genomes.[20] Methods that "read" patient DNA sequences, like genome sequencing and microarrays, help detect specific changes in the sequence of the DNA in a patient that may indicate an increased risk for a specific disease or condition.[21] These techniques do not fundamentally alter or transform the DNA sequences that exist in nature;[22] rather the DNA sequence is merely read.[23]

To read a patient's genetic code, DNA is removed from cells through a process known as DNA extraction.[24] Methods for DNA extraction have existed since the 19th century.[25] Standard methods purify DNA from organisms by breaking open cells and separating the DNA from other

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17. *Id.* at 7–8.

18. *See* SILVERSTEIN ET AL., *supra* note 13.

19. *See id*. at 18 (explaining that when DNA replicates, the two sides of the helicase "split down the middle at one end, like unzipping a zipper."); *See* HARTL & JONES, *supra* note 13, at 210 ("The genetic complement of a cell or virus constitutes its genome.").

20. *See generally* EDWIN H. MCCONKEY, HOW THE HUMAN GENOME WORKS 1–4 (Renee Sekerak ed., 2004) (discussing DNA research and diagnostic techniques); *see* SILVERSTEIN ET AL., *supra* note 13, at 38–39 (discussing the Human Genome Project and the development of DNA research).

21. *See A Brief Guide to Genomics*, NAT'L HUMAN GENOME RESEARCH INST. (Aug. 24, 2010), http://www.genome.gov/18016863 (discussing the importance of genetic research in understanding complex diseases and treatments); *see also Genetic Testing*, GENETICS & PUB. POLICY CTR. (May 2006), http://www.dnapolicy.org/science.gt.php ("The results of genetic tests can be used to diagnose genetic disease, predict risks of disease, and identify carriers of genetic disease" and methods include DNA sequencing and microarrays).

22. *See generally* ROBERT A. BOHRER, A GUIDE TO BIOTECHNOLOGY LAW AND BUSINESS 27 (2007) (explaining DNA replication techniques); RESNIK, *supra* note 1, at 26 (noting that while DNA replication is a natural process, it can be reproduced under laboratory conditions).

23. *See* BOHRER, *supra* note 22, at 27 (discussing how sequencing machines read).

24. *See* George Rice, *DNA Extraction*, MICROBIAL LIFE EDUCATIONAL RESOURCES, http://serc.carleton.edu/microbelife/research_methods/genomics/dnaext html (explaining DNA extraction).

25. Swiss biologist Friedrich Miescher carried out the first successful DNA extraction in 1868, though it was not until the 1940s that scientists discovered its genetic properties. *See The Search for DNA—The Birth of Molecular Biology*, BIOTECH. INDUS. ORG. (1990), http://www.accessexcellence.org/RC/AB/BC/Search_for_DNA.php.

cellular components (e.g. proteins and lipids).[26] Importantly, DNA extraction procedures do not fundamentally transform the DNA or alter the information encoded within it.[27]

Microarrays determine whether a patient's DNA contains a specific sequence by matching DNA molecules extracted from patient cells to those of a known sequence.[28] Microarray chips contain tens of thousands of microscopic spots where DNA molecules of known sequence have been attached to the surface of the slide.[29] After a patient's DNA is extracted, the molecules are "unzipped," separating the two sides of the DNA helix, and tagged with a chemical that glows under laser light.[30] The patient's DNA is then placed on a microarray chip.[31] Under laboratory conditions, the single-strand DNA from the patient's DNA sample will attach to sequences on the chip to which it matches.[32] After allowing the patient's DNA to find its match on the chip, the chip is observed under a microscope.[33] Spots that glow indicate sequences that are contained within the patient's DNA.[34]

DNA sequencing allows geneticists to read any portion of a patient's DNA without knowing the sequence in advance.[35] Similar to microarrays, the process relies on the complementary nature of DNA molecules.[36] However, instead of matching entire DNA molecules to patient DNA,

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26. *See* RESNIK, *supra* note 1, at 28 (outlining the process of isolating and purifying DNA).

27. *See supra* note 21 and accompanying text.

28. *See* HARTL & JONES, *supra* note 13, at 435 discussing microarrays as:

> each containing a different immobilized DNA sequence suitable for hybridization with DNA or RNA isolated from cells growing under different conditions, from cells not exposed or cells exposed to a drug or toxic chemical, from different stages of development, or from different types or stages of a disease such as cancer.

Id.

29. *Id.* (describing a microarray as a "flat surface about the size of a postage stamp on which 10,000 –100,000 distinct spots are present . . . .").

30. *Id.* (describing the variously colored fluorescent labels).

31. *Id.* ("When a sufficient quantity of labeled DNA strands have accumulated, the fluorescent samples are mixed and hybridized with the DNA chip.").

32. *Id.*

33. *See* Patrick O. Brown & David Botstein, *Exploring the New World of the Genome with DNA Microarrays*, 21 NATURE GENETICS SUPPLEMENT 33, 33 (Jan. 1999) ("After hybridization, fluorescence measurements are made with a microscope . . . .").

34. *Id.*

35. *See* T.A. BROWN, DNA SEQUENCING: THE BASICS 3–5 (1994) (outlining the steps of two popular methods of reading a patent's DNA, neither of which require knowing the sequence in advance); *see also* NAT'L HUMAN GENOME RESEARCH INST., *supra* note 21 ("Sequencing simply means determining the exact order of the bases in a strand of DNA.").

36. *See* LUKE ALPHEY, DNA SEQUENCING: FROM EXPERIMENTAL METHODS TO BIOINFORMATICS 5–6 (1997) (referring to the complimentary ability of DNA molecules).

sequencing uses unzipped patient DNA as a template to build the complementary strand of DNA (i.e. the other side of the DNA zipper) one base pair at a time.[37] Traditional methods, developed by Fredrick Sanger, use procedures that simulate in test tubes the process of DNA replication within living cells.[38]

Initially, a large number of copies of the region of DNA to be sequenced are produced, and in order to read the sequence of these millions of identical molecules, sequencing attempts to replicate these DNA molecules again.[39] However, these reactions periodically incorporate specially labeled base pairs (e.g., A's might be labeled green, T's red, G's blue and C's yellow) that terminate the growing DNA strand.[40] When completed, the reaction results in DNA molecules of every length in the sequence.[41] For example, if the DNA sequence to be read were GCTA, the sequencing reaction would create molecules with the sequences G, GC, GCT, and GCTA.[42] By putting them through a molecular sieve, these molecules can then be separated and arranged based upon size, and then visualized to determine their color.[43] So if the sequencing reaction creating

37. *See* HARTL & JONES, *supra* note 13 ("[E]ach strand of the double helix serves as a template for the synthesis of a new strand . . . .").

38. *See* F. Sanger & A.R. Coulson, *A Rapid Method for Determining Sequences in DNA by Primed Synthesis with DNA Polymerase*, 94 J. MOL. BIOL. 441, 441 (1975) (describing "[a] simple and rapid method for determining nucleotide sequences in single-stranded DNA by primed synthesis with DNA polymerase . . . ."); *see* F. Sanger et al., *DNA Sequencing with Chain-Terminating Inhibitors,* 74 PROCE. NAT'L. ACAD. SCI. U.S.A. 5463, 5463–67 (1977) (describing DNA sequencing with chain-terminating inhibitors).

39. *See* HARTL & JONES, *supra* note 13, at 239 ("To obtain the sequence of a long stretch of DNA, a set of overlapping fragments must be prepared, the sequence of each is determined, and all sequences are then combined."). *See generally* BROWN, *supra* note 35 (describing the process of replicating the DNA molecules through the synthesis of complimentary polynucleotide chains from existing single-stranded DNA molecules).

40. *See* BROWN, *supra* note 35, at 27 ("Strand synthesis is not allowed to continue to completion as a chain terminating nucleotide . . . is included in the reaction mixture.").

41. *Id*. at 4 ("The result is therefore a family of new chains, all of different lengths . . ."); *see also* NAT'L HUMAN GENOME RESEARCH INST., *supra* note 21 ("Each of the fragments differs in length by one base and is marked with a fluorescent tag that identifies the last base of the fragment.").

42. *See* BROWN, *supra* note 35, at 4–5 (Figure 1.4 illustrates the strand synthesis reaction which results in a family of chains with overlapping sequences).

43. *See* HARTL & JONES, *supra* note 13, at 240 ("The fragments from all four sequencing reactions are combined, the fragments are separated by size using electrophoresis in a gel or capillary tube, and the dideoxy terminator is identified by its fluorescence.").

molecules that, from smallest to largest, were blue, yellow, red and green, a researcher would know the sequence he was interested in read "GCTA."[44]

However, knowing a patient's DNA sequence is only the beginning.[45] Even a decade after the publication of the first draft of the human genome, researchers are only beginning to decipher the exceedingly complex language encoded by human DNA.[46]

Understanding the language of the human genome is like translating a foreign language. The human genome contains approximately 3 billion base pairs, which encode approximately 20,000 genes.[47] The function of many of these genes is poorly understood, if not completely unknown.[48] Even when a gene's function is known, it is seldom clear how mutations in that DNA sequence will affect a patient's health.[49]

With only a rudimentary understanding of the language of the human genome, geneticists seek to connect the individual differences in patients' DNA with their physical traits and diseases.[50] But individual people differ at thousands of locations in their genomes and have hundreds of different

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44. *See id*. at 240–41 (illustrating the process through which a DNA sequence can be read directly from the colored gel lanes).

45. *See* MCCONKEY, *supra* note 20, at 4 ("Completion of the human genome sequence is a major milestone in human genetics, but it certainly does not mean that we know how all the genes function."); *see also* SANDY B. PIMROSE, PRINCIPLES OF GENOME ANALYSIS: A GUIDE TO MAPPING AND SEQUENCING DNA FROM DIFFERENT ORGANISMS 7 (2d ed. 1998) ("Detailed understanding of an organism will only be achieved when every gene has been identified and its transcript and the timing of transcript synthesis known.").

46. Geoffrey Carr, *Biology 2.0: A Special Report on the Human Genome*. THE ECONOMIST, June 17th 2010 ("[Researchers] found that their methods for linking genetic variation to disease were inadequate…however, these obstacles are falling away.").

47. *See* NAT'L HUMAN GENOME RESEARCH INST., *supra* note 21.

48. *See* NAT'L HUMAN GENOME RESEARCH INST., *Transcriptome*, http://www.genome.gov/13014330 (last reviewed Nov. 26, 2010) ("The function of most genes is not yet known.").

49. *See* MCCONKEY, *supra* note 20, at 46 (describing how genetic and environmental factors both can affect the probability that a clinical condition or disease will develop); s*ee also* J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304, 1348 (2001) ("The sequence is only the first level of understanding of the genome. All genes and their control elements must be identified; their functions, in concert as well as in isolation, defined; their sequence variation worldwide described; and the relation between genome variation and specific phenotypic characteristics determined.").

50. *See* NAT'L HUMAN GENOME RESEARCH INST., *Structural Variation*, http://www.genome.gov/25521748 (last reviewed Aug. 24, 2010) ("However, we still do not completely understand the 'normal' range of human variation present in populations to provide a basis for understanding the variations that result in disease.").

physical traits.[51] In order to determine the genetic changes that result in a given disease or physical trait, geneticists use statistical methods and algorithms to compare the DNA of hundreds of people with a disease or trait and determine which changes commonly contribute to the disease.[52]

By using well-established statistical methods and large numbers of patients, geneticists are beginning to identify changes in individuals that might lead to a greater susceptibility to a given disease or physical trait.[53] And as technologies advance and the cost of determining an individual's DNA sequence continues to fall, studies that associate disease with particular changes in patients' DNA have become common.[54] Many studies have focused on rare diseases that are caused by a small number of genetic changes.[55] Genome Wide Association Studies[56] have also sought out the genetic changes that influence a person's risk for complex, common diseases like heart disease, obesity, and autism, while trying to understand how a patient's environment may exacerbate or minimize the risk of these diseases.[57]

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51. Lynn B. Jorde & Stephen P. Wooding, *Genetic Variation, Classification, and 'Race*,' 36 NATURE GENETICS S28, S28 (2004) ("[E]ach pair of humans differs, on average, by two to three million base pairs."); *See* NAT'L HUMAN GENOME RESEARCH INST., *Genetic Variation Program*, ("Most of any one person's DNA, about 99.5 percent, is exactly the same as any unrelated person's DNA.").

52. *See generally* Richard Mayeux, *Mapping the New Frontier: Complex Genetic Disorders*, 115 J. CLIN. INVEST. 6, 1405–8 (2005) (discussing specific methods that geneticists use to identify "disease genes").

53. *Id*. at 1404 ("The remarkable achievements in human genetics over the years have been due to technological advances in gene mapping and in statistical methods that relate genetic variants to disease."). A partial list of DNA-based tests can be found at http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetest.shtml. HUMAN GENOME PROJECT INFO., *supra* note 9.

54. *See* HUMAN GENOME PROJECT INFO., *Facts About Genome Sequencing*, http://www.ornl.gov/sci/techresources/Human_Genome/faq/seqfacts.shtml (last modified Sept. 19, 2008) (describing the increase of sequencing output from 200 million base pairs in 1998 to 1.5 billion bases for the month of January 2003).

55. Sarah B. Ng et al., *Targeted Capture and Massively Parallel Sequencing of 12 Human Exomes,* 461 NATURE 272, 272 (2009).

56. *See* NAT'L HUMAN GENOME RESEARCH INST., *Genome Wide Association Studies*, http://www.genome.gov/20019523 (last reviewed Aug. 17, 2010) ("A genome-wide association study is an approach that involves rapidly scanning markers across the complete sets of DNA, or genomes, of many people to find genetic variations associated with a particular disease.").

57. *See* Mayeux, *supra* note 52, at 1404, 1407 (stating that "the challenge now is to dissect common complex genetic disorders such as obesity, diabetes, schizophrenia, and cancer" and describing the "relatively new field of genetic epidemiology" as studying the joint effects of environmental and genetic risk factors related to disease).

Once DNA changes associated with specific diseases are known, the hope is to sequence new patients' DNA and predict the types of diseases to which a given patient may be susceptible.[58] Traditional genetic tests, such as Myriad's BRCA1/2 test for breast/cervical cancer,[59] sequence individual genes in order to make predictions about a small number of diseases.[60] Other companies attempt to leverage the advances of Genome Wide Association studies to predict consumers' risks of common diseases.[61] However, the direct-to-consumer genetic tests from companies like 23andMe,[62] Navigenics,[63] and Pathway Genomics[64] have come under severe scrutiny recently for giving consumers conflicting predictions about their disease risk.[65]

II. INTELLECTUAL PROPERTY AND THE GENETICS COMMUNITY

As technologies and methodologies have progressed, the genetics community has embraced a balanced approach to intellectual property, protecting invention while promoting the exchange of scientific data and discovery.[66] For example, the Bayh-Dole Act[67] has helped to incentivize the application of genetic discoveries to the marketplace by vesting the rights to the intellectual property resulting from federally funded research in

58. *See* HUMAN GENOME PROJECT INFO., *supra* note 9 (discussing the hope that after technological improvements health professionals will be able to give patients individual information regarding their risks of developing specific diseases).

59. *See* RESNIK, *supra*, note 1, at 159–60 (providing background on Myriad Genetics).

60. *Id.* (describing the BRCA1/2 test).

61. *See*, *e.g.*, *DeCODE Your Health,* DECODEME, https://www.decodeme.com/complete-genetic-scan (offering for sale a complete genetic scan to determine one's risk to "many of the most common diseases" including heart attack, diabetes, and baldness).

62. *See* Andrew Pollack, *California Licenses 2 Companies to Offer Gene Services*, N.Y. TIMES, Aug. 20, 2008, at C3 (describing the services being offered by 23andMe and Navigenics).

63. *Id.*

64. *See* Andrew Pollack, *Outlook Uncertain*, N.Y. TIMES, Mar. 20, 2010, at B1 (discussing the role of Pathway Genetics in the direct-to-consumer genetic testing market).

65. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-847T, DIRECT-TO-CONSUMER GENETIC TESTS: MISLEADING TEST RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MARKETING AND OTHER QUESTIONABLE PRACTICES, HEARING BEFORE THE SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS AND H. COMM. ON ENERGY AND COMMERCE, 4–5 (2010), *available at* http://www.gao.gov/new.items/d10847t.pdf (discussing a special investigation of direct-to-consumer genetic testing companies that called into question the validity of their services).

66. *See* NAT'L HUMAN GENOME RESEARCH INST., *Intellectual Property and Genomics*, http://www.genome.gov/19016590 (last updated Nov. 16, 2010) (discussing competing interests in the genetics community regarding the strength of intellectual property protection).

67. 35 U.S.C. §§ 200–12 (2006).

the academic institutions that receive the federal grant.[68] Many new and emerging biotechnology companies are based on proprietary intellectual property in genetics,[69] and use intellectual property as the basis for garnering venture funds for their growth and development.[70]

But even as eligibility for patents can incentivize invention and innovation,[71] excessively designating new discoveries as proprietary may also have a chilling effect on research.[72] As the human genome project accelerated, the genetics community recognized the importance of balancing patent rights with the open exchange of scientific data and information.[73] In 1996, members of the genetics community, including

68. *See* RESNIK, *supra* note 1, at 70 (discussing the history of the Bayh-Dole Act); *see also* 35 U.S.C. §§ 200–12 (2006).

69. *See* MICHAEL H. BRODOWSKI ET. AL., BIOTECHNOLOGY AND THE LAW 25 (Eileen Smith Ewing and Hugh B. Wellons eds., 2007) (explaining that life science companies depend on patents as the foundation of the company); *see* Bryn Williams-Jones, *History of a Gene Patent: Tracing the Application and Development of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 126 (2002) (following the Supreme Court's decision in *Diamond v. Chakarbarty*, biotechnology start-up companies increased in number between 1992 and 2002 and were largely based on a genetic patents).

70. *See e.g.*, RESNIK, *supra* note 1, at 67 (explaining that biotech companies, such as Celera Genomics, which spent $200 million on research and development between 1997–2001 without making a profit, depended heavily on patents for their development).

71. *See id.* at 70–71 (explaining DNA patents have provided industry with an incentive to invest billions annually in basic and applied research, and the importance of the private sector's contribution); Clarisa Long, *Patents and Cumulative Innovation*, 2 WASH. U. J.L. & POL'Y 229, 230–31 (2000) (explaining that proprietary intellectual property drive innovation because without these rights, inventors would lack incentives to create as they would not be able to recoup the full value of their invention); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 828–29 (1999) ("Patents promote invention by giving individuals a monetary incentive to devote resources to such invention. Without a patent right, the inventor might not be able to recoup her investment in a socially valuable, but cheaply copied, product."). *But see* Timothy Caulfield, *Human Gene Patents: Proof of Problems?*, 84 CHI.-KENT L. REV. 133, 135–36 (2009) (stating there is little empirical evidence that patents are required for the innovation process).

72. *See* RESNIK, *supra* note 1, at 141 (discussing the research community's aversion to sharing data in order to protect intellectual property claims, with empirical evidence, and growing trend in the life sciences is to withhold or delay publication of data to allow time for patent protection); *see also* Bryan Nese, Bilski *on Biotech: The Potential for Limiting Negative Impact of Gene Patents*, 46 CAL. W. L. REV. 137, 155–56 (2009) (discussing how gene patents can cause excessive delays in research when scientists must obtain a license to conduct research on patented genes or over hesitation to share data in an effort to protect patent eligibility).

73. *See* RESNIK, *supra* note 1, at 4–5. In the 1990's as the Human Genome Project was underway, competition between the public and private efforts developed over the issue of public access to data. *See id.* at 4. The company Celera Genomics planned to charge institutions a fee to access data in advance and to patent portions of the human genome DNA sequences. *See id.* However, by 2000, Celera and the National Human Genome Research Institute arrived at a consensus on data sharing and both published versions of the human genome in scientific journals.

members of the human genome project, agreed that human genome sequences "should be freely available and in the public domain in order to encourage research and development and to maximize its benefit to society."[74] These principles formed the basis of the National Human Genome Research Institute's Policy for Release and Database Deposition of Sequence Data.[75]

Embracing not only patents but also public access, geneticists have led the scientific community in the development of publicly accessible databases.[76] The National Institutes of Health[77] (NIH) supports a variety of publicly accessible databases for gene sequences and information from humans and other organisms.[78] For example, dbGaP (database of

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See id. at 4–5. *But see* Melissa L. Sturges, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT'L L. REV. 219, 237–38 (1997 –1998). Private companies had several reasons why they felt patent protection was necessary to forward research on genome sequences, including the monetary incentive provided by patents as a motivation for researchers to complete the human genome sequence faster. *Id.* at 238.

74. *See* HUMAN GENOME PROJECT INFO., *Summary of Principles Agreed at the First International Strategy Meeting on Human Genome Sequencing*, http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml (last modified Oct. 29, 2003).

75. *See* NAT'L HUMAN GENOME RESEARCH INST., *NHGRI Policy for Release and Database Deposition of Sequence Data*, http://www.genome.gov/page.cfm?pageID=10000910 (last reviewed Aug. 2006). The National Human Genome Research Institute's (NHGRI) policy for release and deposition of DNA sequence data intended to make genome sequence information publically accessible for free within 24 hours of obtaining data 2 kb or larger. *Id.*

76. *See, e.g.*, Bruno J. Stasser, *GenBank—Natural History in the 21st Century?*, 322 SCIENCE 537, 537 (2008) (describing the meeting of scientists in March 1979 to develop a national DNA sequence database); *The First Public Nucleotide Sequence Database Turns 25*, EUROPEAN MOLECULAR BIOLOGY LAB. (May 22, 2007), http://www.ebi.ac.uk/embl/News/news html (explaining the nucleotide sequence database, EMBL-Bank, was the first publically accessible database of DNA and RNA sequences); National Institute of Health News, *GenBank Celebrates 25 Years of Service with Two-Day Conference; Leading Scientists Will Discuss the DNA Database at April 7-8 Meeting*, NIH NEWS (April 3, 2008), http://www nih.gov/news/health/apr2008/nlm-03 htm (discussing the origination of GenBank, a nucleic acid sequence database, that was created by scientists in 1982 as a way for research groups to compare protein and DNA sequencing data).

77. The National Institutes of Health (NIH) is federal agency composed of over 27 institutes and under the U.S. Department of Health and Human Services. *See About NIH, The Nation's Medical Research Agency*, NAT'L INST. OF HEALTH, http://www nih.gov/about/NIHoverview html (last updated June 19, 2007). The NIH is a leading institute in medical and scientific research to improve the health of the nation. *See id.*

78. *See NLM Databases & Electronic Resources*, U.S. NAT'L LIBRARY OF MED., http://www.nlm nih.gov/databases/ (last updated Sept. 17, 2010). The National Library of Medicine website at the National Institutes of Health contains an alphabetical listing of all of NIH's publically accessible databases, including all the genetic databases.

Genotypes and Phenotypes)[79] is a publicly accessible, web-based database that connects human gene sequences known as genotypes, with their associated diseases and conditions, known as phenotypes.[80] Data within dbGaP are clearly identified as "pre-competitive"[81] and the NIH expects funded researchers to provide a data sharing plan.[82] However, there are certain protections of proprietary data, but these exceptions must be discussed with the NIH.[83]

III. GENETIC PATENTS IN THE COURTS

The genetics community has sought to foster innovation by balancing intellectual property claims with the promotion of public access to research data.[84] However, the U.S. Patent Office and the courts have, at times, extended patent protections to claims that seem to upset this fragile balance.[85] While there is little doubt about the patentability of new, useful

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79. NAT'L CENTER FOR BIOTECH. INFO., *dbGap Genotypes and Phenotypes*, http://www ncbi nlm nih.gov/gap (last visited Sept. 24, 2010).

80. *See* Matthew D. Mailman et al., *The NCBI dbGaP Database of Genotypes and Phenotypes*, 39 NATURE GENETICS 1181, 1181 (2007) (explaining dbGaP allows for public access to large-scale data sets in order to analyze how genetic traits are associated with phenotypic disease traits).

81. *See* NAT'L CENTER FOR BIOTECH. INFO., *supra* note 79 ("The data in dbGaP will be pre-competitive, and will not be protected by intellectual property patents.").

82. U.S. DEP'T OF HEALTH & HUMAN SERVS., *NIH Data Sharing Policy and Implementation Guidance: Goals of Data Sharing*, http://www.grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance htm (last updated Mar. 5, 2003) ("To facilitate data sharing, investigators submitting a research application requesting $500,000 or more of direct costs in any single year to NIH on or after October 1, 2003 are expected to include a plan for sharing final research data for research purposes, or state why data sharing is not possible.").

83. *See id.* ("NIH recognizes the need to protect patentable and other proprietary data. Any restrictions on data sharing due to co-funding arrangements should be discussed in the data-sharing plan section of an application and will be considered by program staff.").

84. *See* Rebecca S. Eisenberg & Richard R. Nelson, *Public vs. Proprietary Science: A Fruitful Tension?*, 131 DAEDALUS 89, 99 (2002) (explaining the importance of both private and public research as private competition encourages more frequent discoveries while free access to data allows for free access to genetic information and improves the completeness of proprietary databases). *See generally* Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65 (2002). *But see,* Matthew J. Higgins & Stuart J. H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCIENCE 370, 370 (2009) (proposing that the focus on public access to generic pharmaceuticals has tipped the balance "away from the incentives needed to support innovation").

85. *See* Andrews, *supra* note 84, at 89–91 (discussing examples of patents that disrupt the balance between protecting proprietary rights and the delivery of health care services, such as private ownership of the rights to the genetic tests for the Alzheimer's disease and breast cancer genes and each owner's refusal to let other labs conduct these tests independently).

and novel machines that carry out genetic methodologies, recent case law leaves many questions about the eligibility of genetic processes and the genetic material which they utilize.[86]

A. Process Claims

The Supreme Court has consistently ruled that algorithms, mathematical formulas and other statistical methodologies, are rarely, if ever eligible for patents.[87] As discussed above, these methodologies are at the heart of genetic diagnostics, associating specific genetic changes with increased risk of disease.[88] In *Gottshalk v. Benson*[89] and *Parker v. Flook*,[90] the Supreme Court ruled that the discovery of new and useful mathematical formulas or the application of such formulas is not eligible for patents.[91]

In *Bilski v. Kappos*,[92] the Supreme Court maintains this precedent by ruling that mathematical algorithm for hedging financial risk is not eligible

86. *See e.g.*, Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 702 F. Supp. 2d 181, 230–31 (S.D.N.Y. 2010) (as amended Apr. 5, 2010) (finding Myriad's gene patents related to the breast cancer genes BRCA1 and 2 invalid because the purified DNA segments claimed were not markedly different from that found in nature and were the result of natural phenomena); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 137–38 (2006) (Breyer, J., dissenting) (arguing a patent on a process of correlating results to detect vitamin B and folic acid deficiencies is invalid because the process is no more than an "unpatentable 'natural phenomenon'"); *see also* Michael L. Shuster & Juleen Konkel, *Of Babies and Bathwater—The Impact of* In re Bilski *on Life Science Patents*, 1 HASTINGS SCI. & TECH L.J.153, 154 (2009) (reviewing recent cases that help define the scope of patentable subject matter in the life sciences).

87. *See, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010) (majority opinion) (finding a patent on risk hedging ineligible because the concept of hedging is essentially a mathematical formula, an unpatentable abstract idea); Diamond v. Diehr, 450 U.S. 175, 185 (1981) (explaining "laws of nature, natural phenomena, and abstract ideas" are subject matter excluded from patent protection); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (as laws of nature, physical phenomena, and abstract ideas have been held not patentable, neither Einstein's "$E=mc^2$" nor Newton's law of gravity could be found patentable subject matter); *see also* cases cited *infra* notes 89–90 and accompanying text.

88. *See* Mailman et al., *supra* note 80, at 1185 (describing various statistical methods used to ensure high quality genotypic data).

89. 409 U.S. 63 (1972).

90. 437 U.S. 584 (1978).

91. *Parker*, 437 U.S. at 594 (holding algorithm used for calculating chemical processes involved in catalytic conversion was not patent eligible because the algorithm only provided an improved method for calculating well known chemical processes); *Gottschalk*, 409 U.S. at 68 (holding mathematical formula to convert binary code into binary numbers for use in computers was an abstract idea, not a patent eligible process).

92. 130 S. Ct. 3218 (2010).

for patent.[93] However, in concurring with the circuit court's decision,[94] the Supreme Court held that a process need not be "tied to a particular machine or apparatus"[95] or transform "a particular article into a different state of thing" in order to be patent eligible.[96] Rejecting this "machine or transformation test,"[97] the Court ruled that the method in question was unpatentably abstract and did not pass the non-obviousness criteria.[98]

While the decision in *Bilski* seemingly upholds the precedent that mathematical formulas and algorithms are not patentable,[99] the Supreme Court's opinion expands the definition of a patent eligible process.[100] The Court notes that "[p]atents for inventions that did not satisfy the machine-or-transformation test were rarely granted in earlier eras. . . but times change."[101] Struggling to apply patent law to "unforeseen innovations,"[102] the Court notes that it "is unaware of any 'ordinary, contemporary or common meaning,' of the definitional terms 'process art or methods' that would require these to be tied to a machine or transform an article."[103] But as the Court seeks to expand the definition of a patentable process to meet the needs of the information age, it refuses to give guidance on the limits of patentable process.[104] The Court states:

> *[T]he patent law faces a great challenge in striking the balance between protecting inventors and not granting monopolies over*

93. *Id.* at 3231 (finding that allowing a patent on hedging financial risk would be the same as patenting an abstract idea).

94. *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).

95. *Bilski*, 130 S. Ct. at 3325.

96. *Id.*

97. *See id.* at 3227.

98. *See id.* at 3230.

99. *See id.* at 3231 ("The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*.").

100. *See id.* at 3224 (finding that the machine-or-transformation test, which allows patents on processes that are linked to a machine or that transform something into a different state, is not the only test for determining patent eligibility); *see also* William J. Simmons, Bilski v. Kappos*: The U.S. Supreme Court Broadens Patent Subject-Matter Eligibility*, 28 NATURE BIOTECHNOLOGY 801, 805 (2010) (The *Bilksi* Court expanded the range of patentable subject matter by "holding that the machine-or-transformation test is not the sole test for patent eligibility in the US and the types of patent-eligible subject matter are vast.").

101. *Bilski*, 130 S. Ct. at 3227.

102. *Id.*

103. *Id.* (citing Diamond v. Diehr, 450 U.S. 175, 182 (1981)).

104. Simmons, *supra* note 100, at 805 (2010) (observing that the Court declined to articulate "a generic test that would distinguish a patentable method from an abstract idea").

> *procedures that others would discover by independent, creative application of general principles. Nothing in this opinion should be read to take a position on where that balance ought to be struck.*[105]

By refusing to rule on the limits of process patentability, the Court leaves genetic patents in an uncertain state.[106] Genetic methodologies, including algorithms that associate genetic changes with disease, may be poised to revolutionize diagnostics and personalize medicine.[107] However, excessive granting of patents may have a chilling effect on research, limiting the scientific progress that the patents are designed to encourage.[108] Further, the current uncertainty resulting from the *Bilski* decision may be more problematic because it may lead to the inconsistent handling of patents by the courts or the United States Patent and Trademark Office (USPTO), and subsequently, years of lawsuits and reluctance from investors.[109]

By expanding the definition of patentable processes, the *Bilski* decision is immediately relevant to the eligibility of patent claims at issue in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*.[110] The patent at issue related to a diagnostic process where a drug was administered to a patient and then the patient was tested for the presence of a particular chemical, known as a metabolite, that would not have been

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105. *Bilski*, 130 S. Ct at 3228.

106. *See* Simmons, *supra* note 100, at 805 (noting the biotech industry's lack of guidance as to what is patentable subject matter under the Court's *Bilski* framework for "future innovations such as those emerging in the life sciences").

107. *See* Aleksander S. Popel & Peter J. Hunter, *Systems Biology and Physiome Projects*, 1 WILEY INTERDISCIPLINARY REVIEWS: SYS. BIOLOGY AND MED. 153, 153 (2009) (recognizing that systems approaches in fields such as genomics and proteomics are poised to revolutionize medicine); *see also* NAT'L HUMAN GENOME RESEARCH INST., *Fact Sheet: Genome-Wide Association Studies,* http://www.genome.gov/20019523 (last reviewed Aug. 17, 2010) (stating that genome-wide association studies are laying the foundation for a new era of personalized medicine).

108. *See* Stiglitz & Sulston, *supra* note 10, at A19 (stating that the granting of gene patents "not only prevent the use of knowledge in ways that would most benefit society, they may even impede scientific progress").

109. *See* Jonathan Masur, *Patent Inflation*, 2–3, 5, 33–34 (Chicago Law Sch. Pub. Law & Legal Theory Working Paper Grp., Paper No. 316, 2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1623929 (anticipating that inconsistent application of patents and the uncertainty of patent validity that stems from such application due to decisions such as *Bilski* could lead to the granting of invalid patents which can "hamper a firm's ability to raise capital or write contracts with potential customers").

110. 581 F.3d 1336 (Fed. Cir. 2009); *see also infra* notes 111–22 and accompanying text.

present in the patient in the drug's absence.[111] The patent correlated the level of metabolite in the patient with the need to change the drug's dose in order to "minimize [drug] toxicity and maximize efficacy of treatment."[112]

A central issue in the lawsuit concerned whether the patent claims are "transformative."[113] While the district court invalidated the patent, arguing that the claim represented merely data gathering and mental steps,[114] the circuit court reversed, arguing that the "claims are to transformative methods of treatment, not correlations."[115]

The patent claims in *Prometheus* are not fundamentally different from other diagnostic methods.[116] The circuit court argued that that the patents are "claims to methods of treatment, which are always transformative" when treatments involve drugs administered for the treatment of disease.[117] However, medical practice and diagnosis is inherently empirical, requiring the administration of treatments, the evaluation of their efficacy, and the adjustment of treatment.[118] Many drugs have toxic or undesired side effects and a patient's correct dose can often only be determined by administering the drug and testing how the patient responds.[119]

If the circuit court's ruling in *Prometheus* is allowed to stand under *Bilski's* expansive and uncertain definition of a patentable process, medical diagnostics, including those that use standard genetic methodologies to

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111. *Prometheus,* 581 F.3d at 1339.

112. *Id.*

113. *See id.* at 1347.

114. *Id.* at 1341.

115. *Id.* at 1349.

116. *Id.* at 1339. *See* Brian P. Murphy & Daniel P. Murphy, Bilski*'s "Machine-or-Transformation" Test: Uncertain Prognosis for Diagnostic Methods and Personalized Medicine Patents,* 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 755, 773 (2009) (noting that the *Prometheus* claims for "determining the proper dosage of thiopurine drugs" including the drugs 6-mercaptopurine and azathiopurine which "have been used for years to treat autoimmune diseases").

117. *Prometheus,* 581 F.3d at 1346.

118. *See* Diederick E. Grobbee, *Epidemiology in the Right Direction: The Importance of Descriptive Research,* 19 EUR. J. OF EPIDEMIOLOGY 741, 741–42 (2004) (explaining that empirical documentation of a medical diagnosis requires a study and sampling of cases).

119. *See* Jürgen Brockmöller & Mladen V. Tzvetkov, *Pharmacogenetics: Data, Concepts and Tools to Improve Drug Discovery and Drug Treatment,* 64 EUR. J. CLINICAL PHARMACOLOGY 133, 139 (2008) (advocating for individualized drug therapy because "the choice of the drug and the choice of drug dosing regimens" ought to be "selected based on the patient's individual requirements"); *see also* William E. Evans & Mary V. Relling, *Moving Towards Individualized Medicine with Pharmacogenomics,* 429 NATURE 464, 464 (2004) (observing that differences in DNA sequences means that individuals respond differently to drugs and therefore patients should have their proper dosage tested).

correlate DNA sequences with specific diseases, may be patentable.[120] Such an expansive definition would likely limit research and access to treatment as a select few laid claim to specific genetic associations and their clinical applications.[121]

B. Claims on Gene Sequences

Genetic processes often require the use of specific genetic materials, such as gene sequences or genetically modified organisms.[122] With the accelerated progress of the life sciences,[123] the courts, Congress, and the USPTO have been increasingly willing to grant patents on claims regarding genes and living organisms.[124] However, because versions of patented sequences exist in the DNA of nearly every human being,[125] the granting of patents for claims of specific gene sequences themselves allows for the patenting of naturally occurring phenomena while preventing individuals from knowing their own DNA sequences.[126]

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120. *See* Jeffrey R. Kuester & Steve D. Perkins, *In the Aftermath of* Bilski v. Kappos, in PATENT LITIGATION 2010, at 20 (PLI Intell. Prop., Course Handbook Ser. No. 24179, 2010) ("Although the law remains unsettled, the biotechnology field *perhaps* enjoys a higher level of sympathy."); *see also* Wayne A. Keown, *Short Circuit: How Will* Bilski v. Kappos *Inform the Federal Circuit on Medical Diagnostic Patents?*, PRETI FLAHERTY (June 28, 2010), http://www.preti.com/How-will-Bilski-affect-medical-diagnostic-patents (concluding that if *Prometheus* is allowed to stand under *Bilski*, the considerations will support medical diagnostic procedures as patentable subject matter).

121. Simmons, *supra* note 100, at 803 ("Regarding limiting interference with the development of nascent technologies, such as biotechnology and biopharmaceuticals, the court indicated that some types of inventions 'raise special problems in terms of vagueness and suspect validity' and could 'put a chill on creative endeavor and dynamic change.'").

122. BOHRER, *supra* note 22, at 42 (Carolina Academic Press 2007) (discussing the genetic process of a cell and genetically modified organisms).

123. *See* Popel & Hunter, *supra* note 107, at 153 ("[T]he revolution in biology and progress in genomics and proteomics is now beginning to affect medicine.").

124. *See* Murphy & Murphy, *supra* note 116, at 759–60 (commenting on the Court's caution "against reading limitations into the patent laws not expressed by the legislature" and that even "where an inventor discover[s] a previously unknown natural law or phenomenon" as in some diagnostic method claims, there may still be a patentable invention if the application of the natural law produces a new and useful end).

125. *See generally* Richard Redon et al., *Global Variation in Copy Number in the Human Genome*, 444 NATURE 444, 444–54 (2006) (noting that gene sequences across individual human beings are nearly identical, which means that any patented DNA sequence will exist in most human beings).

126. *See* Aykut Çoban, *Genomic Information and the Public-Private Imbalance*, 2008 CAPITAL & CLASS 71, 81–82 (stating that the "co-modification and ownership of the components of living entities[,]" such as genes and DNA sequences, "through patents raises ethical and legal issues").

Recent court cases have expanded traditional interpretations of patentable subject matter in order to expand patent protections into the field of genetic engineering.[127] In *Diamond v. Chakrabarty*,[128] the Supreme Court ushered in a new era by ruling that genetically modified organisms could be patented.[129] Since *Chakrabarty*, patent law has also begun to evolve and now specifically enumerates some of the biotechnological processes that are patent eligible, including genetically modified organisms.[130]

While Congress intended patents to extend to "include anything under the sun that is made by man,"[131] naturally-occurring DNA sequences themselves, as they exist in human beings, fall outside patent eligible claims under 35 U.S.C. § 101.[132] Despite these prohibitions, patent claims have been granted on "isolated" DNA sequences on the basis that isolation of DNA from the human body "renders it patentable by transforming it into something distinctly different in character."[133] But geneticists are skeptical of this false distinction because they recognize that isolating DNA from human cells does not fundamentally alter its information content or chemical structure.[134] The fact that isolated DNA can be reinserted into patients and retain its original function is the basis for gene therapy research, disease treatments that may soon allow doctors to "fix" parts of a

127. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 125, 125 (2006) (dismissing writ of certiorari and maintaining the Federal Circuit court decision ruling that Metabolite could patent its discovery of the correlation of amino acid levels with B vitamin levels, expanding patent protection to genetic engineering).

128. 447 U.S. 303 (1980).

129. *Id.* at 318 ("[U]ntil Congress takes such action, this Court must construe the language of § 101 as it is. The language of that section fairly embraces respondent's invention.").

130. 35 U.S.C. § 103(b) (1999).

131. *See* S. REP. NO. 82-1979 (1952); *see also* SECRETARY'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOCIETY, U.S. DEP'T OF HEALTH & HUM. SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 57 (2010) [hereinafter *SACGHS Report*], *available at* http://oba.od nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf.

132. Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 702 F. Supp. 2d 181, 233–37 (S.D.N.Y. 2010) (finding that the methods of analyzing isolated DNA gene sequences to identify mutations relating to breast cancer predisposition were not patentable subject matter under the machine-or-transformation test).

133. *Id.* at 185.

134. *See id.* at 199 ("In the context of a gene or a portion of the genome, sequencing is designed to illuminate the information that nature has dictated in that person's genome, and the sequencing process, by design, does not alter the information content of the native DNA sequence").

patients' DNA that will cause disease.[135] Despite reservations from many geneticists, approximately 20% of all human gene sequences have been patented.[136]

In *Ass'n for Molecular Pathology v. United States Patent Office*, (hereinafter *Myriad*),[137] the United States District Court of Southern New York invalidated patents related to the gene sequence of the *BRCA1* and *BRCA2*,[138] certain versions of which make the women who posses them more likely to contract breast and cervical cancer.[139] In its ruling, the district court found that "isolated DNA containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101."[140] While the court's decision may have implications for gene patenting as a whole, the court confined its ruling to the patents at issue and patents representing other genes remain valid.[141]

By invalidating the patent claims, the court combined a detailed understanding of genetic science with relevant case law.[142] The Supreme Court has consistently held that "products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product"[143] and that "'purification' of a natural compound, without more, is insufficient to render the product of nature patentable."[144] Given the non-transformative and purifying nature of DNA

135. *See* Richard C. Mulligan, *The Basic Science of Gene Therapy*, 260 SCIENCE 926, 926 (1993) (explaining the methods of gene therapy involve introducing DNA sequences into cells to treat human disease).

136. *See* Kyle Jensen and Fiona Murray, *Intellectual Property Landscape of the Human Genome,* 310 SCIENCE 239, 239 (2005) (finding that "nearly 20% of human genes are explicitly claims as U.S. IP" and 4,382 of the 23,688 genes in the National Center for Biotechnology Information database are patented).

137. 702 F. Supp. 2d 181 (S.D.N.Y. 2010) [hereinafter *Myriad*].

138. *Id.* at 185.

139. *Id.* at 203 ("Mutations in the *BRCA1/2* genes correlate with an increased risk of breast and ovarian cancer."); *see also* Jeffery P. Struewing et al., *The Risk of Cancer Associated with Specific Mutations of BRCA1 and BRCA2 Among Ashkenazi Jews*, 336 NEW ENG. J. MED. 1401, 1401 (1997) ("Current estimates of the risk of breast cancer in a woman who carries a BRCA1 or BRCA2 mutation . . . range from 76 to 87 percent.").

140. *Myriad*, 702 F.Supp.2d at 185.

141. *See id.*

142. *See infra* notes 143–46 and accompanying text.

143. *Myriad*, 702 F.Supp.2d at 222.

144. *Id.* at 223.

extraction or sequence-reading processes,[145] the *Myriad* decision affirms many genetic researchers' beliefs that DNA sequences should be publically available and is not eligible for patents.[146]

Importantly, the court's ruling also affirms the beliefs that DNA sequences contained within the human genome belong to no specific individual and should be freely available for all to benefit from.[147] Gene sequences across individual human beings are nearly identical.[148] In fact, all human beings have a version of the cancer-related genes at issue in *Myriad* (BRCA1 or BRCA2)[149] but only those individuals with slight differences are at increased risk for developing breast cancer.[150] Therefore, the question as phrased by many is "how can any individual or company have ownership by means of patent of every person's gene or sequence at that location, whether mutant or normal?"[151]

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145. DNA extraction involves breaking apart the cell membrane and then precipitating the DNA out of the solution. However, these processes do not change or alter the DNA in any way. *See* Peter W. Laird et al., *Simplified Mammalian DNA Isolation Procedure*, 19 NUCLEIC ACIDS RESEARCH 4293, 4293 (1991). DNA sequencing involves the addition base pairs and then cleaving the growing strand in order to determine the sequence of the physically purified single strand DNA. The single strand DNA does not change through the process. *See* BROWN, *supra* note 35, at 1–5.

146. *See Summary of Principles Agreed at the First International Strategy Meeting on Human Genome Sequencing*, GENOMICS.ENERGY.GOV, (Feb. 25-28, 1996), http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml (last visited Sept. 27, 2010) (stating that officials and scientists from around the world met in Bermuda and agreed that the human genomic sequence information should be freely available to everyone in order to maximize the information's benefit to society).

147. *See* Pilar N. Ossorio, *The Human Genome as Common Heritage: Common Sense or Legal Nonsense?*, 35 J.L. MED. & ETHICS 425, 433–34 (2007) (arguing that since the human genome is part of the common heritage of mankind, it should be considered a form of public property); *see also* Melissa Sturges, Comment, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT'L L. REV. 219, 249 (1997) (explaining that the human genome is the blueprint of mankind and should be reserved for public access).

148. Richard Redon, et al., *Global Variation in Copy Number in the Human Genome*, 444 NATURE 444, 444–54 (2006) (finding only a 12% variance in the genome population from DNA collected in Europe, America, Africa, and Asia).

149. *See BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT'L CANCER INST. (May 29, 2009), http://www.cancer.gov/images/documents/abcb7812-a132-4e78-a532-f002c92fa9b9/Fs3_62.pdf ("*BRCA1* and *BRCA2* are human genes that belong to a class of genes known as tumor suppressors.").

150. *See supra* note 140; *see also* RESNIK, *supra* note 1, at 159 ("[M]utations of specific genes known as BRCA1 and BRCA2 are associated with an increased risk of breast and ovarian cancer.").

151. *See* Sturges, *supra* note 147, at 249–50 (explaining that allowing a private company to own a patent on the human genome would enable the company to decide what to do with it).

Additionally, by invalidating the patents in *Myriad*,[152] the court set a precedent that will help to alleviate the potential and actual harms that gene patenting has had on scientific and medical discoveries. A recent study by an advisory panel to the U.S. Secretary of Health and Human Services found that gene patents are hindering the development of new medical diagnostic tests while limiting patient access to existing tests.[153] Further, the panel found "the prospect of patent protection of a genetic research discovery does not play a significant role in motivating scientists to conduct genetic research."[154] Patents on gene sequences do little to promote research and discovery while producing significant problems for patients and researchers.

IV. GENETIC PATENTS AND THE FUTURE OF MEDICINE

Genetic research will continue to provide voluminous data and scientists will gain more understanding of the importance of specific genetic sequences.[155] Even more important will be the knowledge gained about epigenetics (the study of gene expression and control caused by mechanisms other than DNA sequence).[156] The genetics research community is ready to abide by all court rulings and federal policies, but confusion remains regarding definitions.[157]

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152. Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010) (as amended April 5, 2010).

153. *SACGHS Report*, *supra* note 131.

154. *Id.* at 1.

155. *See A Brief Guide to Genomics*, NAT'L HUMAN GENOME RESEARCH INST. (Aug. 24, 2010), http://www.genome.gov/18016863 (recognizing the vast amount of information provided from the Human Genome and HapMap Projects and stating that a better understanding of genetics will be important in explaining the role of genes in both health and disease of the human body).

156. *See* Bob Weinhold, *Epigenetics: The Science of Change*, 114 ENVTL. HEALTH PERSPECTIVES 160, 163 (Mar. 2006) (defining epigenetics as "any process that alters gene activity without changing the DNA sequence, and leads to modifications that can be transmitted to daughter cells" and stating that epigenetic mechanisms have become one of the most important considerations for the treatment of cancer).

157. *See* Christopher E. James, *The Impact on Agricultural Research by Genetic Material Patents and the Need for Clarity and Reform in Patent Law for Genetic Material*, 11 DRAKE J. AGRIC. L. 253, 260 (2006) (stating that a major factor for genetic researchers confusion of their rights, duties, and liability under the patent laws is due to the "lack of definiteness" of the law); *see also* Micheal Risch, *Everything is Patentable*, 75 TENN. L. REV. 591, 650 (2008) (proposing a rule to end the subject matter patentability requirement because of uncertainty in the definition and the inability of the USPTO to distinguish subject matter from the other requirements).

In determining which patent claims might be eligible for many genetic methodologies, technologies, and medicines, *Bilski* leaves scientists and medical professionals with uncertainty about the patentability of their inventions and discoveries.[158] The continuum of steps required to associate a specific DNA sequence with a given disease or trait includes a variety of individual and population studies involving both the direct analysis of the DNA and the statistical analysis of large data bases.[159] However, many of these processes are now of questionable patent eligibility.[160] Especially as courts re-examine the patent eligibility of gene sequences, the genetics research community is likely to continue to encourage researchers to share both methods and results.[161] However, when the USPTO or the courts upset the appropriate balance between intellectual property protection and data sharing that is necessary for a robust research enterprise,[162] the patent process will continue to confuse and potentially delay the rapid progress being made in genetic medicine.[163]

The limits of patentable subject matter will continue to be set through case law and the organized human genetics community, as well as individual scientists, will continue to be involved both as legal parties and

158. *See e.g.*, Steve Lohr, Bilski *Ruling: The Patent Wars Untouched*, N.Y. TIMES BITS BLOG (Jun. 28, 2010, 7:31 PM), http://bits.blogs nytimes.com/2010/06/28/bilski-ruling-the-patent-wars-untouched/ (explaining that as the Supreme Court refused to provide a 'bright line' rule for the patentability of business methods, the Court's decision has increased uncertainty benefiting only the patent litigator).

159. *See* Mayeux, *supra* note 52, at 1405 (discussing the procedure, which involves the use of genetic markers to find specific DNA sequences within the genome and then scientists determine the likelihood those sequences are associated with a particular disease through calculation of the odds or lod score).

160. *See* Steven Seidenberg, *Supreme Court Finally Rules in* Bilski v. Kappos, INSIDE COUNSEL, (Aug. 20, 2010), http://www.insidecounsel.com/Issues/2010/September /Pages/Supreme-Court-Finally-Rules-in-Bilski-v-Kappos.aspx (noting many other fields beyond business methods are at risk of being ruled non patentable as a result of *Bilski*).

161. *See* SACGHS Report, *supra note* 131, at 26–27 (recognizing the norm for academic scientists to share research results).

162. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., 548 U.S. 124, 138 (2006) (Breyer, J., dissenting) (stating that the Supreme Court should decide a patent case in order to contribute to the ongoing debate as to whether the patent system reflects the "'careful balance' that 'the federal patent laws . . . embod[y].'"); *see also* Harvey S. Perlman, *Taking the Protection-Access Tradeoff Seriously*, 53 VAND. L. REV. 1831, 1834 (2000) (recognizing one of the classic rationales for intellectual property as finding the proper balance between protection and access in order to maximize the research output).

163. *See generally* Bryan Nese, *Bilski on Biotech: The Potential for Limiting Negative Impact on Gene Patents*, 46 CAL. W. L. REV. 137, 155–56 (2009) (explaining that the profitability of gene patents can cause researchers to disclose less of their results, and therefore hinder research progress, to avoid rejection under the novelty aspect of the patent process).

as *amici curiae*.[164] As the courts struggle to keep up with the pace of genetic research,[165] the best jurisprudence will result from decisions fully informed by the best scientific and legal principles.

164. Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 190–92 (S.D.N.Y. 2010) (as amended April 5, 2010) (listing eleven different parties as *amicus curiae*, including organizations and two individuals: Kenneth Chahine PhD and Kevin E. Noonan PhD).

165. Ryan M.T. Iwasaka, Note, *From* Chakrabarty *to Chimeras: The Growing Need for Evolutionary Biology in Patent Law*, 109 YALE L.J. 1505, 1519 (2000) (urging that the slow and inconsistent work of the courts and USPTO cannot continue because of the rapid development in genetic technology).