Patently Obvious: Why the District Court's Ruling in Association for Molecular Pathology v. USPTO is Incomplete

Kristin Wall, American University Washington College of Law
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Kristin Wall
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ABSTRACT

In March of 2010, the United States Court of Appeals for the Southern District of New York invalidated Myriad Genetics’ patents on the BRCA1/2 genes, which predict susceptibility to breast and ovarian cancer. Prior to this decision, the USPTO and the legal system at large accepted patents relating to human genes as patentable subject matter. In opposition to this standard, the District Court found that human DNA sequences are inherently products of nature and thus fail under 35 U.S.C. § 101.

The Court should not have stopped there, however. The Intellectual Property Clause of the U.S. Constitution creates a standard for patentability based on inventiveness. Merely pinpointing the location of a particular gene sequence based on public information, as Myriad and other companies have done, does not meet this standard. Furthermore, isolating particular gene sequences is obvious under 35 U.S.C. § 103, and as such renders all gene sequences unpatentable.

The social and economic implications of invalidating existing gene patents and preventing future patenting are many; while the financial incentive afforded those holding exclusive ownership rights may decrease, free exchange of ideas and the public’s ability to receive diverse services will proliferate.
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I. Introduction

It is a well-established rule of patent law that natural phenomena, laws of nature, and basic human knowledge are not patentable subject matter.\(^1\) The United States Patent and Trademark Office (USPTO), however, in seemingly contradictory fashion, currently grants patents on human deoxyribonucleic acid (DNA) sequences, so long as those sequences are claimed in the form of “isolated DNA.”\(^2\) This allowance for the patenting and commercialization of human genetic material raises many social, ethical, and policy issues regarding public access to health care and scientific information.\(^3\)


In an unprecedented ruling in March of 2010, the United States District Court for the Southern District of New York opposed the USPTO’s practice of granting patents on isolated DNA in Ass’n for Molecular Pathology v. USPTO, striking down patents held on two genes linked to breast and ovarian cancer.\(^4\) This decision not only makes available to the public genetic testing formerly monopolized by the patent holders, but also sparks the broader issue of patentability of gene sequences.\(^5\)

This Comment argues that, not only was the District Court correct in invalidating the gene patents on the basis of 35 U.S.C. § 101 (“The Patent Act”) patentability, but these and other existing or potential gene patents should also be held invalid based upon their failure to meet the requirements of the Intellectual Property Clause of the U.S. Constitution and their

\(^4\) See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 238 (S.D.N.Y. 2010) (holding Myriad’s patent claims for the isolated BRCA1/2 gene sequences invalid under 35 U.S.C. § 101); see also Nathan Koppel, Judge Rejects Patents on Genes, WALL ST. J., Mar. 30, 2010, at C1 (suggesting that this decision could have far-reaching consequences for other biotechnology companies whose business is based upon gene-related patents).

\(^5\) See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 206 (remarking that Myriad is sole provider of BRCA1/2 testing).
obviousness under 35 U.S.C. § 103. Part II examines the biology of gene sequences and delineates the current state of patent law as it pertains to biological matter. Part II also discusses the factual background and court opinion in Molecular Pathology. Part III argues that the District Court’s finding on the basis of § 101 was correct, but that the contested patents should also have been invalidated under § 103 and under Article I of the U.S. Constitution. Part IV offers policy arguments in support of invalidating the Myriad patents, as well as current and future patents on gene sequences. Finally, Part V of this

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7 See infra Part II.A-B (outlining the history and biology of human DNA, its role in public health matters, and how current patent statutes have influenced patentability of DNA).
9 See infra Part III (arguing that isolated gene sequences are unpatentable because they are not inventive discoveries, are natural phenomena, and their isolation is obvious, under the statutory definition).
10 See infra Part IV (illustrating the damaging effects DNA patents have on public health and research interests).
Comment concludes that by making DNA unpatentable, courts would be adhering more accurately to the limitations on patentable subject matter set forth in the U.S. Constitution and U.S. Code and would promote better health and research opportunities for the general public.\footnote{See infra Part V (concluding that gene sequences should not be patentable subject matter).}

II. BACKGROUND

A. Background on Human Deoxyribonucleic Acid.

1. Deoxyribonucleic Acid Structure.

DNA refers broadly to a class of double-stranded helical molecules contained in every cell of every living organism.\footnote{See George B. Johnson, The Living World 137-38 (1997) (noting that in all organisms other than bacteria, most of the cell’s DNA is located in the nucleus).} DNA dictates the functioning of the individual cell within which it is contained by directing the production of proteins at the necessary time and in the appropriate amount.\footnote{See id. at 143 (indicating that DNA controls the growth, development, maintenance, and reproduction of an organism).} DNA is made up of subunits called nucleotides, with each nucleotide consisting of a sugar (deoxyribose), a phosphate group, and one of four

\begin{itemize}
  \item Adenine
  \item Thymine
  \item Cytosine
  \item Guanine
\end{itemize}
Repeating alternating sugar and phosphate groups form the backbone of each strand of the double-helical structure, with complimentary base pairs (Adenine-Thymine and Cytosine-Guanine) extending from each side to form a weak hydrogen bond between the two strands.\textsuperscript{15}

The helical structure of the DNA molecule permits it to be compacted into the nucleus of the cell, where it is organized into chromosomes.\textsuperscript{16} The number and length of chromosomes are specific for each species of organism.\textsuperscript{17} In humans, these chromosomes contain the human genetic code, or genome.\textsuperscript{18}

The sequence of the four bases of the genome is the medium

\textsuperscript{14} See id. (listing the bases: adenine (A), guanine (G), cytosine (C) and thymine (T)).

\textsuperscript{15} See id. (explaining that the relative weakness of the hydrogen bonds between the bases allows portions of DNA to be readily unzipped and zipped back together).

\textsuperscript{16} See id. at 121 (indicating that humans have forty-six chromosomes grouped into twenty-three pairs in the nucleus of every cell in the body).

\textsuperscript{17} See id. (noting the exceptions, sperm and egg cells, which have twenty-three unpaired individual chromosomes).

\textsuperscript{18} See id. at 166 (revealing that the human genome consists of about three billion base pairs).
through which DNA stores and transmits information. The arrangement of these four bases, over a vast number of iterations, thus determines the nature, functionality, and, often, the health of an organism. Only some regions of an organism’s genome have functional significance; these functional regions are called genes. Furthermore, not all of the DNA in each functional region actually codes for proteins; sections of non-coding regions of the gene, called introns, lie between the

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20 See Johnson, supra note 12, at 166 (arguing genome resembles a computer in that both can store enormous amounts of information by the almost endless repetition of simple operations).

21 See Harvey Lodish et al., Molecular Cell Biology 114 (4th ed. 2000) (explaining that over 90% of an organism’s DNA is not involved in protein synthesis; the function of the vast majority of this extra DNA is not yet known).
coding regions, called exons. While human ingenuity has led to the development of equipment and methods that are used to extract and read a gene sequence, it is undisputed that the ordering of the nucleotides is determined by nature.

2. Protein Synthesis.

The primary function of genes is the production of proteins through protein synthesis. Protein synthesis involves two steps: transcription and translation. During the first stage

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22 See id. at 115, 298-99 (teaching that exons tend to be highly similar across species and between individuals of a given species, while introns vary greatly, which permits DNA fingerprinting of individual human beings).

23 See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 194 (S.D.N.Y. 2010) (indicating that genes and the information represented by human gene sequences are products of nature universally present in each individual, and the information content of a human gene sequence is fixed).

24 See JOHNSON, supra note 12, at 143 (defining “gene expression” as the process of making proteins).

25 See id. at 143-46 (illustrating transcription and translation process of DNA as a library, as DNA cannot leave nucleus of the cell (library) but copies can be made of the DNA, then taken to where they are needed).
of protein synthesis, ribonucleic acid (RNA) reads and transcribes the DNA base sequence. This process yields a strand of messenger RNA (mRNA), which is an exact complement to the template DNA. The mRNA, once spliced to excise the non-coding introns, enters the cytoplasm of the cell to perform translation, which ultimately results in the formation of a protein, or polypeptide.

3. Artificial DNA Synthesis and Isolation.

The artificial production of DNA has become routine in the scientific community and is accomplished through synthesis of complimentary or copy DNA (cDNA). The process of reverse transcription, executed by the complementary binding of bases,

26 See id. at 143 (explaining that, during transcription, hydrogen bonds between complementary bases are broken so that the two strands of DNA “unzip” in the specific region that contains the genetic code for the protein to be synthesized and nucleotides on RNA match up with the template strand of DNA).

27 See id. (clarifying that RNA substitutes uracil (U) for the thymine (T) base in DNA).

28 See id. (emphasizing that the initial mRNA transcript contains both the introns and the exons).

29 See Neil A. Campbell et al., Biology 801 (1994) (noting that this process is accomplished using the enzyme reverse transcriptase).
results in a single strand of cDNA, which includes only coding regions (exons). \(^{30}\) Further synthesis yields the DNA complement to the first cDNA strand, producing a cDNA “clone”: a double-stranded DNA with only the coding regions present. \(^{31}\) cDNA is then used to identify genes and locate them on chromosomes; this is made possible because cDNA contains the coding regions of a gene that is being expressed. \(^{32}\)

cDNA differs from naturally occurring genomic DNA (in vivo DNA) in that the non-coding introns present in naturally occurring DNA are absent in cDNA. \(^{33}\) Thus, the precise nucleotide sequence of cDNA does not exist in vivo, since natural DNA includes both exons and introns (coding and non-coding

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\(^{30}\) See *Benjamin Lewin, Genes VII* 233, 966 (7th ed. 2000) (indicating that this process allows transcription to occur in reverse: instead of DNA specifying mRNA in the nucleus of the cell, isolated mature mRNA is transcribed into DNA).

\(^{31}\) See *Lodish, supra* note 21, at 219-20 (explaining that because mRNA contains no introns, cDNA necessarily includes only coding regions, or exons).

\(^{32}\) See *id.* at 223-35 (indicating that cDNA copies of genes have been compiled into vast cDNA “libraries”).

\(^{33}\) See *id.* at 219-20 (noting that introns are excised from mRNA during transcription).
sequences, respectively). However, despite this structural difference, the information for which cDNA encodes is identical to that for which its natural DNA counterpart encodes.


1. The Intellectual Property Clause.

The Intellectual Property Clause of the U.S. Constitution 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.”

34 See John M. Conley & Roberte Makowski, Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II), 85 J. PAT. & TRADEMARK OFF. SOC’Y 371, 393 (2003) (emphasizing that the sequence of the initial single-stranded cDNA represents a complement of a naturally-occurring mRNA sequence, and the second, complementary cDNA strand carries the exact mRNA sequence).

35 See id. at 394 (positing that, despite its nominal chemical distinctiveness, isolated cDNA is functionally indistinguishable from natural DNA and RNA; it contains the exact same genetic information as its natural counterpart and it can do precisely the same work as a naturally occurring gene).

36 U.S. CONST. art. I, § 8, cl. 8 (emphasis added) (granting a limited monopoly to create incentives for innovation in science
A patent monopoly may not be expanded by the restraints imposed by this stated Constitutional purpose without regard to the innovation, advancement, or social benefit that may stand to be gained by issuance of that patent.37


Patents are not granted for all new and useful inventions and discoveries.38 The subject matter of the invention or discovery must fall within statutory boundaries that permit patents to be granted only for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”39 A thing occurring in nature, and technology).

37 See Graham v. John Deere Co., 383 U.S. 1, 6 (1966) (emphasizing that Congress may not authorize issuance of patents which effectively remove existing knowledge from the public domain or restrict free access to materials already available).


39 See 35 U.S.C. § 101 (1952) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
which is substantially unaltered, is not a "manufacture."  

A "product of nature" is one example of unpatentable subject matter. A true product of nature cannot be patented because it does not constitute a new and useful machine, composition of matter, or manufacture. The Supreme Court has emphasized that the exclusion of products of nature from patentable subject matter allows these basic tools of science and technology to be available for all scientists to draw upon.

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41 See 1 DONALD S. CHISUM, CHISUM ON PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 1.02[7] (Matthew Bender 2010) (listing novelty and nonobviousness standards as "(1) an old product derived from a new source or process or (2) a new product that differs from old ones only in terms of an incremental degree of purity").

42 See, e.g., MPEP, supra note 40, § 706.03(a).

43 See Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (arguing that
In considering whether patents comply with § 101, courts determine (1) whether the claimed invention possesses utility; and (2) whether the claimed invention constitutes statutory subject matter, that is, whether it is a “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, or whether the claimed invention instead falls within the ‘products of nature’ exception to patentable subject matter, i.e., ‘laws of nature, natural phenomenon, and abstract ideas.’”

According to current USPTO regulations, isolated genes are patentable material. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is deemed eligible for a patent because: (1) the excised DNA phenomena of nature are basic tools of scientific and technological work).

35 U.S.C § 101; see also Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (holding that a microorganism qualifies as patentable subject matter because it is not a hitherto unknown natural phenomenon, but a non-naturally occurring manufacture).

See Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001) (indicating that “a patent claim directed to an isolated and purified DNA molecule could cover, e.g., a gene excised from a natural chromosome or a synthesized DNA molecule.”).
molecule does not occur in that isolated form in nature, or (2) the purified state of synthetic DNA is different from the naturally occurring compound.\textsuperscript{46} Although DNA is found in nature, patents are not granted on this natural form, but rather on the isolated and purified form of the gene, the chemical composition of which, it is argued, has never been known before.\textsuperscript{47}


Patentability of an invention also depends on its nonobviousness.\textsuperscript{48} Obviousness is a question of law, but the

\textsuperscript{46} See id. (controverting the argument that naturally occurring DNA is part of human heritage and thus unpatentable, and that if DNA patenting is allowed, a person whose body contains a patented gene could be guilty of infringement).


\textsuperscript{48} See 35 U.S.C. § 103 (1952) (stating that a patent may not be obtained if subject matter would have been obvious at the time invention was made to a person of ordinary skill in the art).
obviousness inquiry takes into account several fact-based elements.\footnote{See Graham v. John Deere Co., 383 U.S. 1, 25 (1966) (holding patents claiming spring clamps obvious in light of prior art); see also Jeffrey S. Dillen, DNA Patentability—Anything But Obvious, 1997 Wis. L. Rev. 1023, 1030 (1997) (noting that evidence must share a nexus with the advantages of the invention).} In order to make out a case of obviousness, one must: (1) determine the scope and contents of the prior art; (2) ascertain the differences between the prior art and the claims at issue; (3) determine the level of skill in the pertinent art; and (4) evaluate any evidence of secondary considerations, such as a long felt but unsolved need in the industry, failure of others to produce the claimed invention, commercial success of the invention, and undue experimentation.\footnote{See Graham, 383 U.S. at 17-18 (holding that the differences between the claims at issue and the pertinent prior art would have been obvious to a person having ordinary skill in the art).} The basis for finding claims obvious is the argument that no patent should be granted on an invention that does not require an inventive leap from technology already available to the public, such as merely incremental variances between the prior art and the claimed subject matter.\footnote{See Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437,}
The first factor in the Graham test of an invention’s obviousness turns on whether a hypothetical person would be led naturally to the solution adopted in the claimed invention, or at least would naturally view that solution as an available alternative. This hypothetical person is assumed to have ordinary skill and knowledge in the art to which the invention pertains, with full knowledge of all the pertinent prior art, and is faced with the problem to which the claimed invention is addressed. This factor essentially gauges what a person of ordinary skill in the art is assumed to know.

1453-54 (Fed. Cir. 1984) (defining the “real meaning of ‘prior art’ in legal theory” as “knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in an art”).

52 See CHISUM, supra note 41, at § 5.04[1] (emphasizing that the claimed subject matter as a whole must be considered in determining obviousness).

53 See id.

54 See 5 JAMES B. GAMBRELL & JOHN H. DODGE, II, Ordinary Skill in the Art—An Enemy of the Inventor or a Friend of the People?, in NONOBSERVENESS—THE ULTIMATE CONDITION OF PATENTABILITY 301, 324-25, 333-35 (John F. Witherspoon ed., 1980); see also Dillen, supra note 49, at 1039 (claiming that to be patentable, one of ordinary skill
Second, the obviousness test considers the creative leap made by one of ordinary skill in the art in order to get from the prior art to the invention.\textsuperscript{55} This factor assumes that the problem to which the invention is addressed was presented to the hypothetical inventor for solution.\textsuperscript{56} The obviousness issue is often posed in terms of a combination or modification of teachings in the prior art, and numerous decisions emphasize that an invention that is merely a combination of reference teachings will generally render such invention obvious.\textsuperscript{57}

\begin{footnotesize}
\begin{enumerate}
\item See \textit{Int’l Cellucotton Prods. Co. v. Sterilek Co.}, 94 F.2d 10, 12 (2d Cir. 1938) (noting that the mere existence of a wealth of past achievement does not detract from the skill necessary to select from that mass).
\item See \textit{Chisum, supra} note 41, at § 5.04(1)(c) (pointing out that while a given solution is often a good business idea because it meets needs not previously recognized, solution from a technological standpoint may have been obvious after problem was recognized, and patents issue only for new, nonobvious solutions to technological problems, not for business ideas).
\item See \textit{Chisum, supra} note 41, at § 5.04(1)(e) (illustrating that
\end{enumerate}
\end{footnotesize}
The third factor in the Graham test measures the level of skill in the art as the level of education and sophistication of average practitioners. The important consideration is whether an invention would or would not have been obvious, as a whole, to a person of ordinary skill in the art when the invention was made. The higher the level of ordinary skill in the art, the more difficult it is to overcome nonobviousness for an invention.

If prior art reference A discloses elements X and Y, and prior art reference B suggests that Z can be substituted for X to achieve desirable results, then a product combining Z and Y is generally obvious.

58 See Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696-97 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984) (noting factors that may be considered in determining level of ordinary skill include: (1) the education level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field).

59 See id. at 697 (distinguishing the person with ordinary skill from a judge, layman, or genius in the art).

60 See Gambrell & Dodge, supra note 54, at 303 (noting that on the
Finally, the fourth factor takes into account secondary considerations to gauge the response of the industry to the invention. These secondary considerations allow inquiry into objective evidence of nonobviousness and are useful for determining the environment in which the invention was made.

other hand, a low level of skill in the art increases the likelihood of nonobviousness). Compare Nat’l Research & Dev. Corp. v. Varian Assoc., 883 F. Supp. 976 (D.N.J. 1995) (holding an improvement to a nuclear magnetic resonance spectrometer obvious over prior art due to extremely high level of skill in the field, wherein person of ordinary skill would have a Ph.D.) with Endress & Hauser, Inc. v. Hawk Measurement Sys., 892 F. Supp. 1107, 1116 (S.D. Ind. 1995), aff’d, 122 F.3d 1040 (Fed. Cir. 1997) (finding that the person of ordinary skill in the relevant field would have a bachelor’s degree).

61 See 5 IRVING KAYTON, PATENT PRACTICE 17-18 (5th ed. 1993) (considering whether the invention solved a long felt but unsolved need within the industry, whether others within the industry were surprised, and whether the conventional wisdom in the art taught away from the claimed invention).

62 See Graham v. John Deere Co., 383 U.S. 1, 17 (1966) (holding that the claimed invention presented no operative mechanical distinctions from the prior art to overcome obviousness).
C. Association for Molecular Pathology v. USPTO.

1. Factual Background.

In 1990 a group of researchers learned that a gene linked to breast cancer, later designated the Breast Cancer Susceptibility Gene 1 (BRCA1), was located on a region of human chromosome seventeen. Myriad Genetics (Myriad), a company co-founded by a member of the research team, later narrowed down the physical location of the BRCA1 gene to a small region of the genome and analyzed the sequence of the DNA in this region to identify the nucleotides comprising the BRCA1 gene. Following the isolation of the BRCA1 gene, scientists continued to search for a second gene (BRCA2), also believed to be linked with...
breast and ovarian cancer.\textsuperscript{65} Myriad filed a total of seven patents relating to the BRCA1 and BRCA2 genes in both the United States and Europe.\textsuperscript{66} The patents claimed the sequences of genes that can cause susceptibility to breast and ovarian cancer.\textsuperscript{67} The claims pertained not just to the methods or processes for cloning or using the DNA sequences, but to the actual sequence of chemical bases making up the breast cancer susceptibility genes, such sequences containing information dictating the genes’ protein production in the body.\textsuperscript{68}

Mutations in sequence of the BRCA1/2 genes are associated

\textsuperscript{65} See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 202 (documenting that in November 1995, researchers identified a mutation in breast cancer patients that appeared to be located in the as-yet unpublished BRCA2 gene).


\textsuperscript{67} See ’282 Patent, supra note 64.

\textsuperscript{68} See id. (claiming BRCA1/2 as compositions, and claiming methods and materials used to detect a human breast and ovarian cancer predisposing gene).
with an increased risk of breast and ovarian cancer.\textsuperscript{69} The proteins for which the BRCA1/2 genes code are critical for DNA repair and transcription regulation; inactivation of these genes through mutation, and subsequent protein alteration, leads to abnormal cellular gene expression, leading ultimately to loss of control over cellular growth (i.e., tumors).\textsuperscript{70} Thus, the existence of BRCA1/2 mutations is an important consideration in the provision of clinical care for breast and ovarian cancer because a patient tested for these mutations will learn of her risk for hereditary breast and ovarian cancer and gain information useful in determining prevention and treatment options.\textsuperscript{71}

\textsuperscript{69} See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 203 (explaining that women with BRCA1/2 mutations face up to an 80% risk of breast cancer and up to a 50% risk of ovarian cancer).

\textsuperscript{70} See W. Hofmann & P.M. Schlag, BRCA1 and BRCA2: Breast Cancer Susceptibility Genes [Review], 129 J. CANCER RES. & CLINICAL ONCOLOGY 487 (2000) (noting functions of the BRCA1/2 genes are similar, although BRCA2 tumors have different cellular expression).

\textsuperscript{71} See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 203 (suggesting this information is useful for women facing difficult decisions regarding whether to undergo prophylactic surgery, hormonal therapy, chemotherapy, and other measures).
Myriad currently offers multiple forms of BRCA1/2 testing to the general public, including BRCAnalysis, available to clinicians and patients at a cost of over $3000 per test. As a result of its patents on the BRCA1/2 genes, Myriad possesses a monopoly on BRCA1/2 genetic testing. Myriad does not accept Medicaid policies in half of the United States, thereby limiting testing availability for lower-income or uninsured patients, or even for patients with forms of insurance Myriad does not accept.

72 See id. (describing Myriad’s standard test, Comprehensive BRACAnalysis, and its supplemental test, BRACAnalysis Rearrangement Test (BART), which together can detect virtually all large rearrangement mutations in the BRCA1 and BRCA2 genes, and noting in 2008, the total cost to Myriad of providing these tests was $32 million with resulting revenues of $222 million).

73 See 35 U.S.C. § 154(a)(1)-(2) (2000) (indicating that a patent holder has a right, for twenty years from the date of the application filing, to prevent any other individual or institution from making, using, offering to sell, or selling the invention); see also Ass’n for Molecular Pathology, 702 F. Supp. 2d at 204 (citing Plaintiffs’ argument that Myriad’s monopoly hinders patients’ ability to receive the highest quality breast cancer genetic testing and impedes the development of improvements to BRCA1/2 testing).
for payment. Of the patients able to obtain BRCAnalysis, many receive ambiguous results but are unable to obtain a second opinion or pursue alternative testing options due to Myriad’s patent protection.  

2. Opinion.

Myriad initiated patent infringement suits against the Plaintiffs beginning in 1998. In response, the Plaintiffs, a diverse group of patients, researchers, non-profits, colleges, and geneticists represented by the American Civil Liberties Union (ACLU), moved for summary judgment pursuant to Federal Rule of Civil Procedure 56. The Plaintiffs sought to declare invalid fifteen claims contained in Myriad’s seven patents

74 See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 204 (noting Myriad pursued Medicaid coverage for years, but has been unable to secure “participating provider status” in 25 states).

75 See id. at 189 (enumerating multiple instances of doctors unable to perform BRCA1/2 genetic testing, and patients unable to obtain testing or seek second opinions).

76 See id. at 181 (illustrating the Plaintiffs’ alleged infringements, including offering free or unlicensed BRCA1/2 screening services).

77 See Fed. R. Civ. P. 56(a) (allowing a party claiming relief to move for summary judgment on all or part of a claim).
relating to the human BRCA1/2 genes.\textsuperscript{78}

In employing the § 101 analysis for patentability, the court observed that it was undisputed that the claimed compositions and methods in Myriad’s patents possessed utility.\textsuperscript{79} The sole task, then, was to resolve whether the claimed compositions and methods constituted statutory subject matter or fell within the judicially created products of nature exception to patentable subject matter.\textsuperscript{80}

The court held that purification of a product of nature, without more, cannot transform it into patentable subject matter; rather, the purified product must possess “markedly different characteristics” in order to satisfy the requirements

\textsuperscript{78} See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 181 (explaining Plaintiffs’ motion is based on § 101; Article I, Section 8, Clause 8 of U.S. Constitution; and First and Fourteenth Amendments of Constitution because patent claims products of nature, abstract ideas, basic knowledge or thought).

\textsuperscript{79} See id. at 220 (indicating that in a § 101 analysis, one must first determine whether claimed invention possesses utility).

\textsuperscript{80} See id. (noting that the second step in § 101 analysis requires consideration of whether the claimed invention constitutes statutory subject matter).
of § 101. In light of this rule of law, the court found that Myriad had not established structural and functional differences between isolated BRCA1/2 DNA and native BRCA1/2 DNA sufficient to render the claimed DNA markedly different, and thus found the claimed compositions unpatentable products of nature.

The court noted that the isolation of the BRCA1/2 genes required considerable effort on the part of Myriad and its collaborators as well as ingenuity in overcoming obstacles associated with the isolation process. Despite this fact, the process and techniques used were well understood, widely used, and fairly uniform insofar as any scientist engaged in the

81 See id. at 227 (citing Diamond v. Chakrabarty, 447 U.S. 303 (1980); The American Wood-Paper Co. v. The Fibre Disintegrating Co., 90 U.S. 566 (1874)).

82 See id. at 229 (remarking that importance of DNA’s nucleotide sequence to its natural biological function and utility associated with DNA in its isolated form, and preservation of this defining characteristic of DNA in its native and isolated forms, mandates the conclusion that challenged composition claims are directed to unpatentable products of nature).

83 See id. at 202-03 (noting that the extracted DNA of the entire human genome contains over three billion nucleotides, of which the gene of interest comprises a very small portion).
search for a gene would likely have utilized a similar approach.\textsuperscript{84}

\textbf{III. Analysis}

The court in \textit{Molecular Pathology} correctly applied § 101, finding that the DNA sequences for the BRCA1/2 genes claimed in Myriad’s patents were unpatentable subject matter.\textsuperscript{85} DNA is a product of nature, but not an ordinary chemical compound, and is thus unpatentable under § 101.\textsuperscript{86} However, additional support for the court’s decision is found in § 103 of the Patent Act and in the bounds on Congress’ power to establish a patent system, set forth in Article I, § 8, Clause 8 of the U.S. Constitution.\textsuperscript{87}

A. \textit{Myriad Did Not Make an “Inventive Discovery” Within the Meaning of Article I, § 8, Clause 8 of the U.S. Constitution, Because the Genes Exist in Nature, and Were Isolated Based on Public Information.}

Temporary patent monopolies are granted as a reward for, and as an inducement to, bringing forth new knowledge.\textsuperscript{88} The

\textsuperscript{84} See \textit{id.} (positing that it is the consensus among the scientific community that another research group sequenced the BRCA2 gene before Myriad).

\textsuperscript{85} See \textit{id.} at 238 (holding patents for the isolated BRCA1/2 gene sequences and methods for analyzing the gene sequences invalid).

\textsuperscript{86} See \textit{infra} Part III.B.

\textsuperscript{87} See \textit{infra} Parts III.A & C.

\textsuperscript{88} See \textit{Graham v. John Deere Co.}, 383 U.S. 1, 9 (1966) (claiming
purpose of the Intellectual Property Clause of the Constitution is not to grant patents for small details or obvious improvements. In light of this purpose, it cannot be said that an “invention” which merely pinpoints the location, using publicly available information, of a naturally occurring substance meets the constitutional standard for inventiveness.

As any scientist would do for any other known DNA sequence, Myriad mapped, isolated, and purified the BRCA1/2 genes based on the information provided by public genome databases and using techniques that were well known in the art. Even if Myriad had not taken these steps, the BRCA1/2 genes would still have

that the grant of an exclusive right to an invention was the creation of society, at odds with the inherent free nature of disclosed ideas, and is not to be freely given).

89 See id. (stipulating that only inventions and discoveries which further human knowledge, and are new and useful, justify the special inducement of a limited private monopoly).

90 See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 200 (S.D.N.Y. 2010) (indicating that techniques required for gene sequencing are well-known and understood by scientists skilled in molecular biology, and scientists and clinicians sequence and analyze genes every day using these methods).
existed in their native states.\textsuperscript{91} The structure of isolated and purified DNA sequences is not substantially different from that of native DNA, and thus it cannot be said that isolated gene sequences are invented.\textsuperscript{92} The only claim Myriad can make is that it located the BRCA1/2 genes, although even that cannot be attributed solely to Myriad, because it utilized publicly available information to do so.\textsuperscript{93}

The rule that the discovery of a law of nature cannot be patented rests not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of discovery that patents are meant to protect.\textsuperscript{94} Constitutional requirements allow only discoveries to

\textsuperscript{91} See Conley, supra note 34, at 394 (illustrating while BRCA1/2 genes were isolated, meaning non-coding regions were excised, non-coding regions do not participate in protein synthesis).

\textsuperscript{92} See infra Part III.B.1 (positing that the genetic information encoded in DNA is not altered through isolation, and thus isolated DNA is not substantially different from natural DNA).

\textsuperscript{93} See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 200 (illustrating Myriad’s use of publicly available information).

\textsuperscript{94} See Parker v. Flook, 437 U.S. 584, 593 (1978) (holding patent invalid because application simply provided a new method for calculating alarm limit values, in which the only novel feature
be patented; and the ingenuity needed for the new conception, and not the amount of physical readjustment employed, is the test of a valuable discovery. DNA is a product of nature, and whether it exists in its natural state or is isolated and purified, it contains the same information and codes for the same specific, predetermined proteins. The mapping of a sequence of DNA cannot be deemed a discovery within the confines of the Constitution; the information carried by DNA exists inherently within every living thing, whether a scientist identifies it or not. In this way, mere isolation of a gene sequence does not qualify as an inventive discovery.

Myriad discovered the sequences for the BRCA1/2 genes insomuch as it narrowed down the location of the genes based on

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See Gillman v. Stern, 114 F.2d 28, 30 (N.Y. 1940) (holding that the inventor showed more than ordinary insight in his invention, because no one else had come up with it).

\[96\]

See infra Part III.B.1.

\[97\]

See Memorandum of Law in Further Support of Plaintiff’s Motion for Summary Judgment at 14, Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09-4515), 2010 WL 2643072 (indicating that Defendants concede that DNA embodies information, whether isolated or not).
publicly available information. However, this discovery cannot be attributed to Myriad alone, because it resulted from the application of information and processes already existing in the public sector. Myriad cannot be awarded ownership rights for naturally occurring genetic information that is essentially discovered each time an individual is diagnosed with breast or ovarian cancer.


1. DNA is a Product of Nature Because In Vitro DNA is Not Substantially Different from In Vivo DNA.

Proteins are naturally occurring, as are the DNA sequences that encode for them. Biotechnology inventions, therefore, walk a fine line between products of nature and human invention. Isolated DNA, especially when obtained through

98 See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 201 (crediting the BRCA1/2 genes’ locations to linkage analysis of familial cancer inheritance records from Utah Genealogical Society and Utah Mormon Genealogy).

99 See ’282 Patent, supra note 64 (indicating that genetic mapping of the BRCA1/2 genes involved selecting genetic markers from a known genetic map).

100 See Dillen, supra note 49, at 1029.

101 See id. (illustrating that while an engineered organism,
well-known processes, falls on the product of nature side of that line.\textsuperscript{102}

Although products of nature may not be patented, this exclusion presents no obstacle to patenting DNA sequences, in forms that do not occur in nature, as new compositions of matter.\textsuperscript{103} The prohibition against patenting products of nature only prevents the patenting of DNA sequences in a naturally occurring form that requires no human intervention.\textsuperscript{104} In this way, patents have issued on isolated and purified DNA sequences, containing foreign DNA and exhibiting a capability it does not normally possess, is clearly “artificial” enough to be an invention, an isolated strand of DNA used as an intermediate in the creation of such an organism is naturally occurring).

\textsuperscript{102} See id.

\textsuperscript{103} See, e.g., U.S. Patent No. 4,703,008 (filed Oct. 27, 1987) (patenting DNA sequences encoding erythropoietin); see also Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding a patent claiming isolated adrenalin valid).

\textsuperscript{104} See Rebecca S. Eisenberg, Re-examining the Role of Patents in Appropriating the Value of DNA Sequences, 49 Emory L. J. 783, 785-86 (2000) (positing that many lawyers treat the products of nature limitation as a technical, claim-drafting problem).
separate from the chromosomes in which they occur in nature.\textsuperscript{105} Isolated and purified DNA sequences (\textit{in vitro}), however, are not substantially different from those naturally occurring in the body (\textit{in vivo}), and thus fall squarely within the definition of products of nature.\textsuperscript{106} The BRCA1/2 genes were isolated through a process employing cDNA, an artificially produced complementary DNA strand.\textsuperscript{107} cDNA, in contrast to native DNA, does not contain introns.\textsuperscript{108} However, it is pivotal


\textsuperscript{106} See Diamond, 447 U.S. at 310 (finding patentee’s production of a new bacterium with markedly different characteristics from any found in nature and with the potential for significant utility, outside nature’s handiwork). But see CONLEY, supra note 34, at 394 (illustrating that the DNA removed from its natural environment is functionally indistinguishable from natural DNA and RNA).

\textsuperscript{107} See ‘282 Patent, supra note 64 (claiming isolation methods including hybridizing cDNA or screening cDNA libraries).

\textsuperscript{108} See LEWIN, supra note 30, at 966 (emphasizing cDNA is transcribed from template DNA strands from which introns have
to note that introns do not contain genetic material used in coding for proteins, and thus a strand of DNA consisting solely of exons, as in the case of cDNA, and a strand including both introns and exons, will code for the same proteins. These same proteins for which the DNA and cDNA strands code will then go on to perform identical tasks.

The fact that the BRCA1/2 DNA molecules covered by Myriad’s patents contain only protein-coding exons, and not the introns found in native DNA, does not render these DNA sequences and their native counterparts “markedly different.” Therefore, not only are the coding sequences contained in the claimed DNA identical to those found in native DNA, the particular arrangement of those coding sequences is the result of the

been excised).

109 See LODISH, supra note 21, at 114 (explaining that genetic material for coding proteins is contained only in exons).

110 See id. (indicating that proteins perform tasks based on the information from which they have been encoded).

111 See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 230 (S.D.N.Y. 2010) (noting that the splice variants represented by these cDNAs are the result of the naturally-occurring splicing of pre-mRNA into mature mRNA).
natural phenomena of RNA splicing.112 Thus, regardless of the absence of introns in the cDNA used to locate the BRCA1/2 genes, the information provided by the cDNA is identical to that of the native DNA from which the cDNA was generated.113 Furthermore, as noted by the court in Molecular Pathology, the presence or absence of chromosomal proteins between isolated DNA and the corresponding native DNA merely constitutes a difference in purity and cannot establish subject matter patentability.114

The genetic information encoded in DNA is not altered through isolation or purification processes.115 Isolated DNA,

112 See id. (positing that claimed cDNA sequences are actually found in the human genome as naturally occurring pseudogene).
113 See id. at 198 (explaining that cDNA contains the identical protein coding information content as the DNA in the body, even though differences exist in its physical form).
114 See id. at 229–30 (rejecting Myriad’s argument attempting to establish the distinctive nature of the claimed DNA).
115 See Memorandum of Law in Further Support of Plaintiff’s Motion for Summary Judgment at 14, Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09-4515), 2010 WL 2643072 (arguing that the chemical structure of DNA’s nucleotide sequence is identical whether the nucleotides are in the body or in a test tube).
once introduced into other cells and incorporated into chromosomes, will perform the very same function it did in the human body or organism.\textsuperscript{116} The physical embodiment of a gene is DNA, and the information contained within that gene is comprised of the arrangement of bases in the DNA.\textsuperscript{117} This is the same whether DNA is \textit{in vivo} or \textit{in vitro}. DNA, and in particular the ordering of its nucleotides, therefore serves as the physical embodiment of laws of nature—those that define the construction of the human body.\textsuperscript{118} Regardless of the presence or absence of introns, DNA is a product of nature, and no amount of isolation or purification will render the information it provides an invention attributable to man.\textsuperscript{119}

\textsuperscript{116} \textit{See id.} (enumerating experiments indicating that DNA carries the same information whether inside or outside the organism).

\textsuperscript{117} \textit{See id.} (rejecting claim that genes represented by isolated DNA in the patent are structurally and functionally distinct in any significant way from those found in nature).

\textsuperscript{118} \textit{See Ass’n for Molecular Pathology v. USPTO}, 702 F. Supp. 2d 181, 228 (S.D.N.Y. 2010) (holding Myriad patents invalid as unpatentable subject matter).

\textsuperscript{119} \textit{See CONLEY, supra note 34, at 394} (positing isolated DNA employs same processes of protein synthesis in nature and lab).
2. DNA is Not an Ordinary Chemical Compound Because it is Inherently an Information Carrier.

The central premise of Myriad’s argument that its claimed DNA is markedly different from DNA found in nature is the assertion that isolated DNA molecules should be treated no differently than other chemical compounds when considering patentability.\(^{120}\) This characterization of DNA as an ordinary chemical compound, however, fails to take into account the unique properties of DNA.\(^{121}\)

The properties of chemical compounds are often difficult to predict, except to the extent that structurally similar compounds typically have similar properties.\(^{122}\) The unpredictable nature of chemical reactions may result in a newly synthesized compound that is very similar in structure to known

\(^{120}\) See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 228 (alleging difference in structural and functional properties of isolated DNA render claimed DNA patentable subject matter).


\(^{122}\) See id. (noting that structurally similar prior art compounds provide motivation to search for homologous compounds, in the expectation that they will have similar properties).
and existing compounds and yet exhibits very different properties.\textsuperscript{123} This unpredictability does not apply, however, to DNA-based technology.\textsuperscript{124}

Although DNA is technically a chemical compound, it is more fundamentally a carrier of information.\textsuperscript{125} The information encoded in DNA is not information about its own molecular structure incidental to its own biological function, as is the case with adrenaline or other chemicals found in the body.\textsuperscript{126}

\textsuperscript{123} See Eli Lilly & Co. v. Zenith Goldline Pharmals., Inc., 2001 WL 1397304, *5 (S.D. Ind. 2001) (indicating that § 103 analysis focuses not on chemists’ ability to imagine a compound or synthesize a molecule to order, but on whether the prior art provided apparent reason or motivation to take the step that led to synthesis of the new compound).

\textsuperscript{124} See Rai, supra note 121, at 836 (positing that the informational nature of DNA negates any unpredictability).

\textsuperscript{125} See id. (noting that the informational link between DNA and amino acids has been well established for decades).

\textsuperscript{126} See In re O’Farrell, 853 F.2d 894, 895-96 (Fed. Cir. 1988) (arguing that DNA, and in particular the ordering of its nucleotides, defines construction of the human body); see also Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911) (holding that adrenaline, once extracted from animal
Rather, the information encoded by DNA reflects its primary biological function: directing the synthesis of other molecules in the body. Thus, the informational nature inherent in DNA eliminates the unpredictability of ordinary chemical compounds. The court in Molecular Pathology emphasized that this informational quality is unique among the chemical compounds found in our bodies, and it would be erroneous to view DNA as no different from other chemicals previously the subject of patents.

The useful properties of a gene, such as its ability to tissue for medicinal use, may be patentable, although it differs from previous preparations only in its degree of purity).

See Parke-Davis, 189 F. at 103 (concluding that any information that may be embodied in adrenaline or similar molecules serves no comparable function to that of DNA).

See Rai, supra note 121, at 836 (arguing that the informational link between DNA and amino acids allows for isolation of a target DNA sequence, a process unique to DNA, as opposed to ordinary chemical compounds).

See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 228 (S.D.N.Y. 2010) (emphasizing the unique properties of DNA that distinguish it from all other chemicals and biological molecules found in nature).
bind to another complementary strand of DNA for diagnosis, or its ability to code for a particular protein, are not those that the scientist has invented, but rather are natural, inherent properties of genes themselves. The utility of purified BRCA1/2 DNA molecules as biotechnology tools relies on their ability to selectively bind to native or isolated BRCA1/2 DNA molecules, which is a function of the isolated DNA’s nucleotide sequence. Thus, categorization of DNA as an ordinary chemical compound in order to argue for isolated DNA’s patentability is erroneous; the informational nature of DNA renders its chemical structure irrelevant to the novelty inquiry.

C. The BRCA1/2 Genes are Obvious Under 35 U.S.C. § 103.

As patent law currently stands, any given DNA sequence is obvious if the prior art recites a similar or identical


\[131\] See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 197 (describing the hybridization of a primer or probe to the BRCA1/2 DNA target, resulting in the formation of a “hybridization product” that permits detection of target DNA).
sequence.\textsuperscript{132} Under this rule of law, DNA sequences can be nonobvious no matter how easy or routine the isolation process is, and companies are able to seek patents on hundreds of thousands of DNA sequence fragments that they have been able to isolate quickly through automated methods.\textsuperscript{133} Upon analysis under the Graham test, however, it becomes clear that DNA sequences, regardless of the methods by which they are isolated, are obvious subject matter, and thus do not meet the patentability requirements of § 103.\textsuperscript{134}

1. A Person of Ordinary Skill in the Art Would Have Found This “Invention” Obvious Because Myriad Located the BRCA1/2 Genes Using Public Information.

The first consideration in the Graham test evaluates the obviousness of the invention from the viewpoint of one with ordinary skill in the relevant art at the time the invention was located.\textsuperscript{135}

\textsuperscript{132} See, e.g., In re Deuel, 51 F.3d 1552, 1557 (Fed. Cir. 1995) (indicating this is opposed to simply reciting a method for isolating the sequence).


\textsuperscript{134} Cf. Graham v. John Deere Co., 383 U.S. 1, 17 (1966) (developing the four-part Graham test and using it to invalidate patent claiming a plow for obviousness).
made. As technology in the relevant art improves and becomes more widely used within the community, it becomes more difficult to overcome an argument for nonobviousness. When techniques in the relevant art have become commonplace and the inventor has utilized these techniques in the claimed invention, one of ordinary skill in the art will most likely find the invention obvious.

The BRCA1 gene was localized in 1990, based on publicly available data, narrowing down its locus to within approximately 8 million base pairs. Myriad, using this publicly known

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135 See, e.g., Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1209 (Fed. Cir. 1991) (holding patent nonobvious because at the time Amgen isolated DNA sequence for human Erythropoietin, gene probing techniques were new and DNA libraries were undeveloped).

136 See In re Bell, 991 F.2d 781, 785 (Fed. Cir. 1993) (finding that while the protein in the prior art was completely sequenced and corresponded directly to the claimed DNA, the methods in the prior art were not sophisticated enough to enable one of ordinary skill in the art to make the connection).

137 See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 196 (S.D.N.Y. 2010) (emphasizing that DNA can be isolated and purified using any number of well-known techniques).

138 Contra ’282 Patent, supra note 64 (insisting that size of
information, then relied on the use of linkage analysis, in which correlations between the occurrence of cancer and the inheritance of certain DNA markers among family members were used to pinpoint the chromosomal region of the BRCA1 gene within the human genome.\textsuperscript{139} Myriad produced a genetic map by selecting commercially-available potential markers and testing them using DNA extracted from members of the kindreds it studied.\textsuperscript{140} Myriad then used multiple publicly available markers in an iterative process to narrow down the BRCA1 region to one small enough to allow isolation and characterization of the BRCA1 locus using techniques well known in the art.\textsuperscript{141}

\textsuperscript{139} See '282 Patent, supra note 64, at col. 7:53-8:7 (noting that linkage analysis requires detailed genealogical records).

\textsuperscript{140} See id. (explaining that where possible, candidate markers can be selected from a known genetic map; however, where none is known, new markers can be identified using a common technique).

\textsuperscript{141} See id.
In this way, Myriad “discovered” the BRCA1 gene by starting from known information on the gene’s locus and using known methods and publicly available materials in each step taken to narrow down the location.\textsuperscript{142} Myriad’s patent thus falls squarely within the first element of the \textit{Graham} obviousness test: one skilled in the art would have used the known information, just as Myriad did, to locate and isolate the BRCA1 gene, and would have found this process obvious.\textsuperscript{143}

2. \textit{There is Little Difference Between Prior Art and Present Claims.}

The second element of the \textit{Graham} test evaluates the proximity of the invention to the prior art; it considers the creative leap that one of ordinary skill must have taken to get from the prior art to the present invention.\textsuperscript{144} As DNA

\textsuperscript{142} See \textit{id.}

\textsuperscript{143} See \textit{In re Deuel}, 51 F.3d 1552, 1558 (Fed. Cir. 1995) (stressing that a general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene that is subsequently obtained as a result of that search). \textit{But see Amgen, Inc. v. F. Hoffman-LaRoche Ltd.}, 580 F.3d 1340, 1369 (Fed. Cir. 2009) (finding that the process by which the claimed gene was isolated was not obvious, but noting that the idea of isolating the gene was obvious to try).

\textsuperscript{144} See \textit{Int’l Cellucotton Prods. Co. v. Sterilek Co.}, 94 F.2d 10,
isolation, sequencing, and cloning techniques increase in number and become more commonplace, this criterion becomes more difficult to overcome.\textsuperscript{145} The Human Genome Project, mapping the DNA sequence of the human genome, commenced in October of 1990.\textsuperscript{146} Since the human genome was published, any subsequent human gene mapping will necessarily fall within the information disclosed by this project.\textsuperscript{147} The scope of knowledge and

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12 (2d Cir. 1938) (invalidating patent because one skilled in the art would have made the same improvements over prior art).
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\textsuperscript{146} See Robert Cook-Deegan, \textit{The Gene Wars: Science, Politics, and the Human Genome}, 168, 230 (1994) (noting that the Human Genome Project was funded by the National Institute of Health, and the first draft was completed in February 2001).

technical expertise in gene sequencing has expanded exponentially since then, making it increasingly difficult to justify nonobviousness of gene-related inventions.  

DNA can be homologous between tissues in an individual, and can even be conserved between species. Thus, the information provided by such genome libraries can easily be used to map other unknown gene sequences. When Myriad Genetics obtained its patents for the BRCA1/2 genes in the mid-90s, much DNA sequencing information had already been amassed. In fact, Myriad utilized this publicly available information to isolate

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148 See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1369 (Fed. Cir. 2003) (finding osteoporosis drug obvious in light of similar drugs on the market with equivalent dosages).


the BRCA1/2 genes.\textsuperscript{151} Employing known and documented markers and chromosome sequences, Myriad was able to map the BRCA1/2 genes.\textsuperscript{152}

Considering the information available in the public domain on gene sequences at the time of Myriad’s patents, one of ordinary skill in the art would not have had to make a significant leap to obtain the sequence for the BRCA1/2 genes.\textsuperscript{153} The gene sequences claimed in Myriad’s patents are substantially close to information that was publicly available at the time the patents were filed, and thus the information claimed by the patents is obvious.\textsuperscript{154}

\textsuperscript{151} See ‘282 Patent, supra note 64 (describing identification using cDNAs corresponding to the BRCA1/2 gene locus by screening various cDNA libraries).

\textsuperscript{152} See id. (illustrating the isolation process using Yeast Artificial Chromosomes from known libraries).

\textsuperscript{153} See, \textit{e.g.}, Merck, 395 F.3d at 1364 (arguing that the scope of knowledge and technical expertise in biotechnology is expanding exponentially and making it increasingly difficult to justify the non-obviousness of gene-related inventions).

\textsuperscript{154} See, \textit{e.g.}, \textit{In re O’Farrell}, 853 F.2d 894, 904 (Fed. Cir. 1988) (rejecting application disclosing techniques for producing recombinant proteins as obvious based on prior art references).
3. **Level of Skill in the Pertinent Art is Very High.**

The higher the level of ordinary skill in the art, the more likely it is that the claimed invention is obvious.\(^{155}\) The level of skill in the recombinant DNA industry is very high.\(^{156}\) Such technical sophistication weighs heavily in the direction of obviousness.\(^{157}\) One effect of this high level of sophistication is that those skilled in the art are well aware of the few known methods that consistently and successfully produce results.\(^{158}\)

\(^{155}\) See Gambrell & Dodge, supra note 54, at 324 (noting that in biotechnology, the level of skill is very high).

\(^{156}\) See Dillen, supra note 49, at 1043 (noting that researchers at biotechnology companies typically have advanced degrees and several years of lab experience).


\(^{158}\) See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 200 (S.D.N.Y. 2010) (stating that the techniques required for gene sequencing are well-known and understood by scientists skilled in molecular biology, and scientists and clinicians sequence and analyze genes literally every day).
4. Objective Evidentiary Factors.

Secondary considerations in the Graham test provide objective evidence of nonobviousness.159 The increasing ease and speed with which DNA has been isolated over the past two decades, however, negates several of these considerations, such as: the long felt but unsatisfied need in the industry, failure of others in the industry to understand the problem, teaching away, unexpected results, and disbelief on the part of others of ordinary skill in the art.160 By the time Myriad filed its patents, the technical capabilities of those skilled in the art were such that none of these factors could be argued, because the techniques were so conclusively proven.161 The successful

159 See Graham v. John Deere Co., 383 U.S. 1, 6 (1966) (considering secondary factors such as commercial success, long felt but unsolved needs, failure of others, etc., to give light to circumstances surrounding the origin of the subject matter sought to be patented).

160 See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1367 (Fed. Cir. 2003) (indicating that commercial success is relevant to the obviousness inquiry because the law presumes an idea would have been brought to market sooner had the idea been obvious to persons skilled in the art).

161 See JOSEPH SAMBROOK ET AL., MOLECULAR CLONING: A LABORATORY MANUAL (2d
mapping of the human genome indicates that there was not an unsatisfied need, nor an inability to understand the problem.\textsuperscript{162} Similarly, the fact that Myriad utilized techniques well known in the art negates any argument that prior art taught away from the methods for isolating and purifying DNA, or disbelief on the part of others skilled in the art.\textsuperscript{163} At the time Myriad initially filed its patents for the BRCA1/2 genes, there existed ample interest in and documented information on gene sequences such that these secondary considerations do not substantiate an argument for nonobviousness.\textsuperscript{164}

IV. Policy Implications and Suggestions

The District Court’s invalidation of Myriad’s patents on

\textsuperscript{162} See SCHWARTZ, supra note 147, at 734 (revealing that the Human Genome Project was undertaken with the goal of identifying all of the genes constituting the human genome and determining the sequence of the genome’s chemical bases).

\textsuperscript{163} See ’282 Patent, supra note 64 (indicating that isolation of the BRCA1/2 genes was performed using a number of publicly available sources and techniques).

\textsuperscript{164} See, e.g., COOK-DEEGAN, supra note 146 (delineating the history of the Human Genome Project).
the BRCA1/2 genes has sparked challenges to other existing gene
patents in courtrooms, legislatures, and in the arena of public
opinion.165 Patents claiming human genetic material raise a
variety of issues regarding scientific and medical research,
access to health care, privacy, autonomy, religious freedom, and
reproductive liberty.166

165 See, e.g., Genomic Research and Diagnostic Accessibility Act
of 2002, H.R. 3967, 107th Cong. (2002); Greenberg v. Miami
(seeking to invalidate patents issued on tissue used to isolate
gene causing a fatal genetic disease); see also Patents on
Breast Cancer Genes Ruled Invalid in ACLU/PubPat Case, ACLU
(March 29, 2010), http://www.aclu.org/free-speech-womens-
rights/patents-breast-cancer-genes-ruled-invalid-aclupubpat-case
(noting that approximately twenty percent of human genes are
patented, including genes associated with Alzheimer’s disease,
muscular dystrophy, colon cancer, asthma, and many other
illnesses).

166 See Lori B. Andrews and Jordan Paradise, Gene Patents: The
Need for Bioethics Scrutiny and Legal Change, 5 YALE J. HEALTH
POL’Y, L. & ETHICS 403, 404 (2005) (indicating that intense
opposition to gene patents is coming from researchers,
politicians, organized religions, indigenous groups, patient
The Intellectual Property Clause of the U.S. Constitution states that patent rights are granted in order to promote the progress of the useful Arts.\textsuperscript{167} Many believe that patents promote invention by providing individuals with a monetary incentive to devote resources to such invention.\textsuperscript{168} By limiting the free use of technical innovations, the temporary monopolies granted by patents increase the value of such innovations to ensure that more will be generated.\textsuperscript{169} Following the creation of a new invention, considerable effort and resources are typically required to develop it into a marketable product, thus necessitating the monetary support that monopolies provide.\textsuperscript{170}

\textsuperscript{167} See U.S. Const., art. I, § 8, cl. 8.

\textsuperscript{168} See Rai, supra note 121, at 829 (noting that without a patent right, an inventor might not be able to recoup her investment in a socially valuable, but cheaply copied, product).

\textsuperscript{169} See Joan Robinson, The Accumulation of Capital 87 (2d ed. 1966) (arguing that this constraint benefits society as a whole).

\textsuperscript{170} See Rebecca Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. R. 1017, 1051-52 (1989) (indicating that the lure of monopoly profits encourages firms to invest in developing existing inventions into practical applications).
Yet, others have suggested that patents undermine the communal values that promote scientific discovery.\textsuperscript{171} As demonstrated by Myriad’s collaborative process in locating and isolating the BRCA1/2 genes, scientists work in communities where sharing information, theories, and even materials fundamentally facilitates basic research.\textsuperscript{172} Myriad would not have been successful in pinpointing the location of the BRCA1/2 genes on human chromosome seventeen had the Human Genome Project not made publicly available its genome map.\textsuperscript{173} Such factors limit the need for the monopolies granted by patents, and indicate that genome sequencing will continue to proliferate in their absence.\textsuperscript{174}


\textsuperscript{172} See Robert K. Merton, \textit{The Sociology of Science: Theoretical and Empirical Investigations} 270–78 (Norman W. Storer ed., 1973) (emphasizing scientists depend on each other to validate claims, and access to research findings and methodologies is therefore crucial).

\textsuperscript{173} See supra Part III.C.2.

\textsuperscript{174} See Sec’y Advisory Comm. on Genetics, Health, and Soc’y,
The sequencing technique Myriad claimed for testing susceptibility to breast and ovarian cancer fails to detect ten to twenty percent of expected mutations in BRCA1.\textsuperscript{175} Thus, gene patenting runs the risk of directly harming a patient by failing to make available a medical diagnostic procedure that can detect a disease in her genetic makeup.\textsuperscript{176}

Furthermore, ownership of a gene patent allows its holder

\textsuperscript{175} See Press Release, Assistance Publique-Hôpitaux de Paris, & Institut Gustave-Roussy, Against Myriad Genetics’ Monopoly on Tests for Predisposition to Breast and Ovarian Cancer Associated with the BRCA1 Gene (Sept. 26, 2002) (on file with Institut Curie) (citing this inaccuracy as a concern that prompted the French to challenge the Myriad patent).

\textsuperscript{176} See David Malakoff, \textit{NIH Roils Academe with Advice on Licensing DNA Patents}, 303 Sci. 1757, 1758 (2004) (indicating that NIH-proposed guidelines recommend wide licensing of patented inventions to nonprofit researchers and public health agencies in order to remedy this problem).
to charge whatever price it wants: Myriad requires that all BRCA1 and BRCA2 diagnostic testing be performed by its Utah laboratory at a cost of over $3,000 per test. This cost can be prohibitive for many potential patients, especially those for whom insurance does not cover the procedure. Additionally, this monopoly prevents women from seeking a second opinion or alternate tests.

Given that the location and isolation of the BRCA1/2 genes would have been obvious to those skilled in the art, and could have been achieved using publicly available information and well-known methods by others besides Myriad who are skilled in the art, the monopolization of testing procedures is not justified.

177 See Andrew Pollack, Patent on Test for Cancer is Revoked by Europe, N.Y. TIMES, May 19, 2004 at C3 (emphasizing this is three times the amount French laboratories charged for the same test).

178 See supra Part II.C.1 (noting that Medicaid does not cover BRCAAnalysis in twenty-five states).

179 See ACLU, supra note 165 (emphasizing that information on BRCA1/2 gene mutations is critical for women deciding on a plan of treatment or prevention, i.e., increased surveillance or preventive mastectomies or ovary removal).

180 See supra Part III (arguing that Myriad’s patents on the
Granting patents on naturally occurring genetic information allows for the creation of corporate monopolies over what is both public knowledge and a product of nature. Once a company has laid claim to a particular gene sequence, it is free to sequester that information from any other organization seeking to utilize it. In some cases, gene patent holders will only allow their own laboratories to use the test for the patented gene; this exclusive licensing can itself interfere with the BRCA1/2 genes should be held invalid under the U.S. Constitution, 35 U.S.C. § 101, and 35 U.S.C. § 103).

See, e.g., Carina Dennis, Geneticists Question Fees for Use of Patented “Junk” DNA, 423 Nature 105, 105 (2003) (illustrating that some gene patent holders claim gene segments that occur in nature and exist in vivo, such as an Australian company that has acquired global patent protection over non-coding regions of the human genome, amassing millions of dollars in licensing deals with drug companies and universities for the right to use this information in research and drug development).

See 35 U.S.C. § 154(a)(1)-(2) (2000) (granting patent holders the right, for twenty years from the date of the application filing, to prevent any other individual or institution from making, using, offering to sell, or selling the invention).
A patent holder might forbid anyone from using the genetic sequence it has patented, even if the patent holder itself does not offer a diagnostic test using that sequence.  

Between 1981 and 1995, more than 1,175 human gene patents were granted worldwide, with more than 25,000 DNA-based patents by 2000. Unrestrained DNA patenting could lead to a situation where research and development of diagnostics.  

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183 See Andrea Knox, Companies Holding Patents to Disease-Related Genes Limiting Access, PHILA. INQUIRER, Feb. 13, 2000 at A1 (quoting Jon Merz) (citing, as an example, countries where the Alzheimer’s gene and hemochromatosis gene were not patented, and researchers were able to discover previously unknown mutations critical in diagnosing individuals who would not otherwise be diagnosed by the patented gene or diagnostic test).

184 Cf. Gaia Vince, Gene Patents "Inhibit Innovation," NEWSCIENTIST.COM (July 23, 2002), www.newscientist.com/news/print.jsp?id=ns99992580 (arguing that this practice could become more prevalent as more pharmacogenomic discoveries are made and inventors sit on their patent rights, prohibiting patients from receiving testing for genetic diseases).

185 See RAI, supra note 121, at 835 (noting that revenues for biotechnology start-up companies, whose main resources are
in which all genes are patented and new research becomes prohibitively expensive.\textsuperscript{186} Such limitations on public access to health and research opportunities are detrimental to society, and such detriment is not overcome by financial incentives.

V. Conclusion

The District Court for the Southern District of New York was correct in invalidating Myriad Genetics’ patents, claiming the structure and use of the BRCA1/2 genes, based on their lack of patentable subject matter under 35 U.S.C. § 101.\textsuperscript{187} DNA sequences, regardless of being isolated or purified, are products of nature; isolated and purified DNA is not patents on potential disease-genes, more than tripled between 1993 and 2001).

\textsuperscript{186} See M.A. Heller & R.S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Sci. 698 (1998) (arguing further that unrestrained gene patenting would also have a significant impact on the provision of genetic services through the public health care system, potentially making genetic tests and therapeutics unaffordable).

\textsuperscript{187} See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 238 (S.D.N.Y. 2010) (holding patents on the BRCA1/2 genes invalid for failure to claim patentable subject matter).
substantially different from naturally occurring DNA.\textsuperscript{188}
Furthermore, DNA is not an ordinary chemical compound because it
is inherently an information carrier, and thus should not be
treated as an ordinary compound in considering its
patentability.\textsuperscript{189}

The District Court erred, however, in failing to invalidate
Myriad’s patents for their failure to meet the broader
requirements of the U.S. Constitution.\textsuperscript{190} Myriad did not invent
or discover the BRCA1/2 genes within the meaning of the
Intellectual Property Clause, nor did the Court consider the
obviousness of Myriad’s patent claims.\textsuperscript{191} A person of ordinary
skill in the art would have found Myriad’s invention obvious
because Myriad located the BRCA1/2 genes using public

\textsuperscript{188} See CONLEY, supra note 34, at 394 (indicating that the
information for coding proteins is identical in isolated and
naturally occurring DNA).

\textsuperscript{189} See RAI, supra note 121, at 836 (indicating that the
information carried by DNA, and not its chemical structure, is
the basis for its usefulness in research and diagnosis).

\textsuperscript{190} See U.S. Const., art. I, § 8, cl. 8 (limiting patentable
subject matter to inventive discoveries).

\textsuperscript{191} See 35 U.S.C. § 103 (1952) (requiring claims that would not
be obvious to one skilled in the art).
information. Additionally, there is little difference between the prior art and Myriad’s claims, and the level of skill of those skilled in the field of genetic research is very high. Combining these primary factors with secondary considerations demonstrates the obviousness of Myriad’s patent claims, thus indicating that Myriad’s patents should have been held invalid under 35 U.S.C. § 103.

In addition to failing to meet Constitutional and statutory standards, patents granted on DNA sequences adversely impact society. The monopoly granted to Myriad on BRCA1/2 gene testing prevents many uninsured or inadequately insured women

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192 See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 201 (acknowledging that Myriad mapped the BRCA1/2 genes’ locus based on publicly available familial records and cDNA libraries).

193 See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1373 (Fed. Cir. 2003) (arguing extensive mapping of gene sequences makes arguments against nonobviousness increasingly difficult); see also Dillen, supra note 49, at 1043 (noting that genetic researchers typically have a Ph.D. in a life science).

194 See Merck & Co., 395 F.3d at 1376 (indicating that prior success in the field is indicative of obviousness of invention).

195 See DENNIS, supra note 181, at 105 (indicating that gene patents allow for corporate monopolies over public knowledge).
from obtaining breast and ovarian cancer susceptibility testing, and prevents those who can afford the test from seeking second opinions.\textsuperscript{196} The monopolies obtained by other gene patent holders prevent public access to information necessary for further research, thus hindering scientific discovery.\textsuperscript{197} This roadblock to discovery is not justified by funding needs, as gene discovery is substantially publicly funded.\textsuperscript{198}

Invalidation of the BRCA1/2 gene patents, as well as of current patents claiming other gene sequences, properly conforms to the guidelines set forth in the U.S. Constitution and U.S.

\textsuperscript{196} See Ass’n for Molecular Pathology, 702 F. Supp. 2d at 204 (indicating that Medicaid does not cover BRCAnalysis, and patients seeking the additional BART testing must pay an additional fee unless they meet “high risk patient” criteria).

\textsuperscript{197} See 35 U.S.C. § 154(a)(1)-(2) (2000) (granting patent holders twenty years from filing to exclude others from making, using, offering to sell, or selling the invention in the U.S.).

\textsuperscript{198} See John M. Golden, Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System, 50 EMORY L. J. 101, 137 (positing that a substantial portion of technology research and development funding comes from the federal government).

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Code. Such invalidation would better serve the scientific community and the public at large without sacrificing inventive motivation.\textsuperscript{200}


\textsuperscript{200} See Williams-Jones, supra note 3, at 145 (arguing unrestrained gene patenting has significant impact on provision of genetic services through public health care system).