INTANGIBLE OR EMBODIED INFORMATION: THE NON-STATUTORY NATURE OF HUMAN GENETIC MATERIAL

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Abstract

Although scientists, social scientists, and historians since the early 1950s have described deoxyribonucleic acid (DNA) sequences as information, this characterization has yet to be recognized by the law of intellectual property. However, a prestigious body of national policy-makers recently acknowledged that the nature of genomic discoveries could be considered information distinct from the tangible molecules from which it is derived. The implications of this characterization for patent law suggest that recent decisions dealing with the statutory subject matter of computer-implemented inventions could prove more relevant than prior cases regarding patents granted to discoveries in the life sciences. The following Article expands upon this suggestion. Examining the science of DNA, including the technical processes of DNA isolation and purification, as well as the language of specific patent claims, establishes that these claims are being made purely for their informational content, as either intangible information per se, or by regarding DNA as information embodied as a molecular structure. Thus characterized, analogous cases dealing with computer technology, including recent decisions from the Federal Circuit, provide the argument that DNA sequences represent exceptions to patentable subject matter as laws of nature and can be viewed as falling outside the enumerated categories of statutory subject matter under 35 U.S.C. § 101.

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INTRODUCTION

While intellectual property law has not treated it as such, academic discourse has situated human genetic material, deoxyribonucleic acid (DNA) and DNA sequences, within a conceptual framework that characterizes its inherent nature as information. In *Who Wrote the Book of Life? A History of the Genetic Code*, historian Lily E. Kay discusses the history of work on the genetic code within the rise of communication techno-science such as cybernetics, information theory and computers, as well as the history of life science, and traces its beginnings to the early 1950s (the dawn of the information age).[1] Describing the workings of DNA and protein synthesis as information flow, Francis Crick's work, according to Kay, "encapsulated the ideology and experimental mandate of molecular genetics: genetic information, qua DNA, was both the origin and universal agent of all life."[2] This information discourse established a new context, a language for human genes where life's messages constitute a text written in codes.[3]

Decades later, following the advent of the Human Genome Project, social scientists similarly described, analyzed, and characterized the nature and value of genomic discoveries as, implicitly, information separate from its biological and material source.[4] Similar to the operations of a computer network, within the system of a human organism, genes transmit data through processes of coding and encoding.[5] What has come to be known as bioinformatics suggests that fundamentally, not only does DNA act like information; a molecule of DNA is simply embodied or materialized information.[6] Social, economic, ethical, and political implications arise from such a characterization: genetic information, i.e., a DNA sequence, independent of its material source, becomes a product of global mercantile exchange.[7] Once removed from the

1. LILY E. KAY, WHO WROTE THE BOOK OF LIFE? A HISTORY OF THE GENETIC CODE, at xv (2000).

2. *Id.* at 174-75.

3. *Id.* at 72.

4. *See infra* notes 6-7 and accompanying text.

5. *See infra* notes 136-142 and accompanying text.

6. EUGENE THACKER, THE GLOBAL GENOME: BIOTECHNOLOGY, POLITICS, AND CULTURE 8-9 (2005) [hereinafter GLOBAL GENOME]. *See also* Eugene Thacker, *Database/Body: Bioinformatics, Biopolitics, and Totally Connected Media Systems*, SWITCH, Jan. 20, 2000, *available at* http://switch.sjsu.edu/nextswitch/switch_engine/front/front.php?artc=243.

7. KAUSHIK SUNDER RAJAN, BIOCAPITAL: THE CONSTITUTION OF POSTGENOMIC LIFE 42 (2006).

control of the human body and populations, a DNA sequence regarded as pure information establishes a new hierarchy: whoever controls this intellectual product, the bio-power of the genome, assumes a new control over life.[8]

The perception, characterization, and recognition of the implications of DNA as information was similarly recognized by a prestigious body of this nations' policy-makers and scientists in a 2006 report published by the Committees of the National Academies, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (Report).[9] Its preface spoke of the need to avoid conflicts between the rights of an inventor and open access to newly-identified genetic information, as well as a need to assess whether appropriate mechanisms were in place to prevent such conflicts.[10]

In examining these mechanisms, the authors described a history of the *patenting* of human genetic material, suggesting a major transformation in how the nature of the subject matter of these patents was, and is, being perceived evolving from biological materials to pure information.[11] In the 1970s, patents were granted for "isolated and purified" DNA sequences encoding naturally-occurring amino acid sequences.[12] "[T]he courts and the United States Patent and Trademark Office (USPTO) treated these inventions as chemicals or 'compositions of matter.'"[13] Based upon this precedent, biotechnology firms in the 1980s secured numerous patents on genes that encoded therapeutic proteins, thus securing "exclusive franchises" for their manufacture.[14] However, the Report noted that in the 1990s, "the development of new tools and techniques for detecting genetic differences among individuals enabled researchers to bypass the stages of protein isolation and characterization and to identify directly the genes associated with diseases (or disease

8. KAY, *supra* note 1, at 327.

9. *See* REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (Stephan A. Merril & Anne-Marie Mazza eds., 2006) [hereinafter *Report*], *available at* http://www.nap.edu/catalog.php?record_id=11487.

10. *Id.* at ix.

11. *Id.* at 73.

12. *Id.* at 71.

13. *Report*, *supra* note 9, at 71 (quoting Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) for the proposition that "[a] gene is a chemical compound, albeit a complex one").

14. *Id.* at 71.

susceptibilities) through positional cloning."[15] The authors noted that bypassing the process of protein isolation rendered the genes useful both as research tools and diagnostics.[16]

The Report described how the advent of high-throughput DNA sequencing allowed for the automatic identification of expressed sequences, which led to the practice of patenting these sequences without patenting the corresponding protein or its function.[17] These sequences, known as ESTs (Expressed Sequence Tags) are critical research tools[18]:

> Because the sequence information contained in an EST is enough to distinguish one gene from all others, each EST may be used to identify the chromosomal location of its corresponding gene. The ability to locate where a particular gene is located on a chromosome is important in the detection of chromosomal mutations and corresponding disease states.[19]

The ability to locate a particular gene on a chromosome assists in the detection of chromosomal mutations and corresponding disease states when the EST is compared to underlying genomic sequence information (or mapping data, e.g., a genetic marker) to which the sequence of the EST can be compared.

By 1999, the practice of patenting these sequences invoked concerns, and the USPTO responded by requiring that a practical and substantial utility of the DNA sequence be demonstrated.[20] As discussed by then National Institute of Health (NIH) Director, Harold Varmus, and the National Human Genome Research Institute Director, Francis Collins, a patent requires more than a theoretical function of the protein as the sole basis of the pronounced utility.[21] The Report notes that "[t]he first patent filings on the results of high-throughput DNA sequencing coincided with a broader trend in the biomedical research community to claim intellectual property rights in research tools and to assert these rights against academic researchers."[22]

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15. *Id.* at 71-72 (citing Francis S. Collins, *Positional Cloning Moves from Perditional to Traditional*, 9 NATURE GENETICS 347, 347-50 (1995)).

16. *Id.* at 72.

17. *See id.* at 52.

18. *Id.*

19. *Id.*

20. *Report*, *supra* note 9, at 52-53.

21. *Id.* at 53 (citing Correspondence from Harold Varmus, Director, NIH, and Francis Collins, NIHGR, to Q. Todd Dickinson, USPTO (Dec. 21, 1999).

22. *Id.* at 73 (citation omitted).

This controversy regarding the patenting of ESTs as research tools emphasized the nature of genomic discoveries as information, distinct from their previous characterization as tangible molecules.[23] Despite the technological advances and changes in how this information is and was identified, it is arguable that the Report recognizes that patent claims on DNA sequences, Single Nucleotide Polymorphisms (SNPs) and complimentary DNA sequences (cDNA) have consistently been motivated by and made on this separate informational content distinguished from its biological and material identity.[24]

This recognition is particularly significant. Joining the social scientists and philosophers, scientists, engineers, biomedical researchers, and policy-makers have come to recognize that claims to DNA sequences can be perceived and characterized as intangible information, separate and thus distinguishable from the tangible molecule in which it is contained. DNA sequences can also be described or characterized as information which has materialized or is embodied as a molecular structure.[25] Simply, when considering the

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23. *Id.* at 73.

24. *See supra* notes 9-22 and accompanying text regarding an explanation of the various types of claimed DNA sequences.

25. *See* Dan Burk, *The Problem of Process in Biotechnology*, 43 HOUS. L. REV. 561, 582-87 (2006). Dan Burk finds the description of DNA sequences as simply "information" too simplistic; rather he describes the patented molecules as "channels for informational transfer processes." *Id.* at 563. Instead of the DNA in isolation, "[i]t rather functions within an interactive structural apparatus that as a whole forms an information transfer system." *Id.* at 583. DNA physically interacts with "other structure mechanisms, and . . . is essentially inoperative outside its functional matrix." *Id.* at 583. In this functional matrix, "information is encoded in the architecture or structure of molecules." *Id.* at 585. Information flow within a cell occurs via the interaction of particular configurations of molecular structure with complementary configurations of molecular structures.

> Biological molecules interact and encode information not only via the spatial exclusions of their molecular form-which is to say, the spaces occupied by their repulsive electron shells-but also via the extended secondary, tertiary and quaternary structures formed by the macromolecular chains, the clustered arrays of water molecules surrounding these macromolecules, the clouds of charged ions that macromolecules draw in their wake. These interlocking physical structures are the . . . "channels" by which information is conveyed from molecule to molecule. . . . [I]n biotechnology the medium is quite literally, the message.

Id. at 585-86. So, sequences are merely the shorthand for a set of spatial relationships, it's not the string, but the "three-dimensional configuration of the molecule" that encodes the information. The implication for patenting is that the information is *only* useful when embodied in such structures, which is to say that, ultimately, no one is

> interested in strings of human-readable letters–they are instead interested in *what can be done with the structures the letters represent*. And that in turn means that by necessity they must be interested in building informational structures–the molecules that are the conduit for information transfer.

nature and character of human DNA, "the medium is . . . the message."[26] Despite this recognition and the growing literature devoted to the implications of human genetic material as information, intellectual property law to date has not treated it as such, but continues to allow the privatization of human genetic material in the form of patents based upon a limited and archaic definitional understanding of DNA sequences as simply biological "wet" material.[27]

The legality of patents issued on DNA sequences should be analyzed within the context of the nature and characterization of what is *actually* being claimed. The legitimization by the scientific community and policy-makers of human genetic material as constituting *information* suggests a possible new paradigm for considering the legality of such patents and specifically whether such claims are directed to patentable subject matter under 35 U.S.C § 101.

While the original precedent establishing the statutory subject matter of patents granted to DNA molecules based upon the concept of their having been "isolated and purified" is equally questionable,[28] the characterization of genetic sequences as *information* provides a legal argument for the premise that DNA sequences represent the express limitations on 35 U.S.C. § 101 subject matter as defined and described by the Court and followed by the lower courts.[29] The following Article attempts to delineate why, when DNA sequences are characterized and perceived as *information* and informational content distinguishable from the tangible molecule in which they are contained, they constitute non-statutory subject matter for which a patent cannot be granted. Instead, DNA sequences, as information, exemplify the exact limitation upon subject matter the Court has

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Id. at 586-87 (second emphasis added). Thus, "it is the information flow that is of interest in biotechnology, and hence of interest in biotechnology patenting." *Id.* at 587 (emphasis omitted).

26. *Id.* at 586 n.127 (citing MARSHALL MCLUHAN, UNDERSTANDING MEDIA: THE EXTENSIONS OF MAN 7 (1964)).

27. *See, e.g.*, *supra* note 13.

28. There are various arguments questioning the patentability of DNA and DNA sequences which are outside the scope of this article. For example, commentators have argued that DNA and DNA molecules are non-statutory, excluded from § 101 suitability as "Products of Nature." Despite the processes known as "isolation and purification," the molecules are essentially identical to those found in nature and thus non-statutory according to the law. *See, e.g.*, Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 400, 461-62 (2002); John Conley & Robert Makowski, *Going Back to Square One: Biotechnology Patents and the Products of Nature Doctrine*, 13 INFO. & COMM. TECH. L. 3, 8-11 (2004).

29. *See, e.g.*, *infra*, notes 102-120 and accompanying text; notes 145-199 and accompanying text; notes 275-457 and accompanying text.

defined as comprising laws of nature as well as falling outside the statutory categories of patent eligible subject matter.[30]

In delineating this argument, Part I discusses the law, science, and language involved in patent claims on DNA sequences. Although the USPTO Utility Examination Guidelines state that DNA sequences are eligible for a patent when "isolated from their natural state and purified, and when the application meets the statutory criteria for patentability,"[31] an examination of the biological properties of DNA and the processes of "isolation and purification" reveals that the nature of what is being claimed, i.e., the resultant information, is identical whether occurring in its natural state, or having been identified, isolated, purified, or replicated by complex technological achievement. Additionally, examining the specific types of claims directed to human genetic material, and the contexts in which they are framed, further reiterates how such claims are essentially directed to the informational content of human genetic material.

Part II will discuss how, in light of the science previously discussed, human DNA gene sequences and fragments, human DNA gene sequences used to detect specific mutations, and human DNA sequences with single nucleotide polymorphisms (SNPs), are not statutory subject matter. This section will examine the seminal *O'Reilly v. Morse*[32] case, invalidating patent claims for the underlying principle of electromagnetism that exemplified the laws of nature doctrine.[33] Similarly, whether or not they have been identified, isolated, purified, or replicated as cDNA, the intangible or embodied information of DNA sequences is a manifestation of a law of nature, a numerical arrangement, a formula, an expression of an idea, a pre-existent scientific truth or principle, and ultimately a research tool, and thus excluded from the categories of statutory subject matter.

Part II Section A will establish how patent claims to identified, isolated, and purified DNA and DNA sequences, fragments, SNPs, or replicated cDNA are simply a representation of an arrangement of base pairs, and that these claims are precisely directed to the informational content of the genetic sequence.[34] A recent decision from the Federal Circuit examining how a claim for a signal should be

30. *See* 35 U.S.C. § 101 (2000) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

31. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

32. O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).

33. *Id.* at 112-18.

34. *See, e.g.*, *In re* Nuijten, 500 F.3d 1346, 1353 (Fed. Cir. 2007) (discussing the patenting of the *information* contained in a signal).

construed provides a strong rationale that patent claims to genetic material can similarly be construed as claiming the informational content.[35] Thus, these claims are not directed to statutory subject matter.

Section B of Part II establishes why DNA sequences, whether occurring naturally or having been identified, isolated and purified, or replicated, are information expressing a pre-existing scientific principle which, when patented, either pre-empts the scientific principle itself or is not new. Thus, the information should be considered a law of nature, an exception to statutory subject matter.

Analogies are drawn between "the informational processing" system implemented by the activity of human DNA genetic sequences and the workings involved in computer technology systems.[36] In fact, in characterizing DNA sequences as information, distinguished from its material source, the National Academy Report further suggests that if these claims are directed purely to the informational content, the use of which would be an infringement, then recent decisions dealing with the subject matter of computer-implemented inventions would prove more relevant than prior decisions regarding patents on genetic discoveries.[37]

Illustrative of these cases are the Supreme Court's decisions in *Gottschalk v. Benson*[38] and *Parker v. Flook*,[39] as well as the Federal Circuit's decision in *In re Warmerdam*.[40] Considering the underlying principles involved in computer technologies, these cases regard mathematical algorithms as laws of nature exceptions to patentable subject matter if they either wholly pre-empt the algorithm or are not new (novel) but merely previously unknown. This section describes how, analogous to these algorithms, the discrete units of information of DNA sequences that encode the arrangement of amino acids comprising individual proteins are similarly laws of nature and pre-existing scientific principles which, if patented, wholly pre-empt their use.

Section C of Part II proceeds to specifically examine the analogy of the computer technology cases to establish that claims to identified, isolated, and purified DNA sequences, SNPs, and cDNA are not statutory subject matter as the processes involved in their creation do

35. *Id.*
36. *See infra* notes 140-145 and accompanying text.
37. *See Report*, *supra* note 9, at 76-77.
38. Gottschalk v. Benson, 409 U.S. 63, 67, 71-73 (1972).
39. Parker v. Flook, 437 U.S. 584, 589, 593-94 (1978).
40. *In re* Warmerdam, 33 F.3d 1354, 1358-59 (Fed. Cir. 1994).

not transform the retrieved information into something other than the information originally existing in their natural environment. The Court in *Diamond v. Diehr*[41] distinguished its previous cases regarding the statutory nature of algorithms.[42] When these mathematical principles were applied by a process in such a way that an article was either transformed or reduced to a different state, they became suitable subject matter for the grant of the patent.[43] Thus, lower courts expanded the patentability of algorithms embedded within process claims, but only when the process had a transformative result.[44] Where claimed inventions did not have a transformative effect, they were found to be non-statutory subject matter.[45] Examining claims to the information of human genetic material establishes that this information, like a formula or numerical expression, has also not been transformed by the process of its identification, isolation, purification, or replication, and thus should not be considered statutory subject matter.

Part III of this article argues that claims directed to DNA sequences, construed as information, are non-statutory subject matter as they do not fall within an enumerated category: it is neither a process, machine, manufacture, nor composition of matter analogous to a claimed signal at issue in a recent Federal Circuit case.[46] Section A of Part III argues that the sequential information of human genetic material is analogous to cases involving the patentability of inventions considered within the "printed matter" doctrine. The doctrine involves a line of cases determining that an arrangement of printed matter, commonly, words or images on paper, is non-statutory.[47] In the computer age, the doctrine's rules similarly apply to information recorded in different substrates or mediums.[48]

Section B of Part III considers one type of claim important for the present and future of medical research and healthcare. This section concludes that claims to methods and materials for determining a relationship between a particular DNA sequence and the presence or absence of susceptibility to a disease are non-statutory mental steps or mental processes. The Court has held that "mental processes . . . are not patentable, as they are the basic tools of scientific and

41. Diamond v. Diehr, 450 U.S. 175 (1981).
42. *Id.* at 186-87.
43. *Id.* at 187.
44. *See infra* notes 209-241 and accompanying text.
45. *See, e.g.*, *In re* Bilski, 545 F.3d 943, 965-66 (Fed. Cir. 2008).
46. *See In re* Nuijten, 500 F.3d 1346, 1353, 1357 (Fed. Cir. 2007).
47. *See* DONALD S. CHISUM, 1 CHISUM ON PATENTS § 1.02[4][c] (2008).
48. *Id.* at § 1.02 [4][c][ii], [4][e].

technological work."[49] A recent Federal Circuit case concerning a claim directed to a business method reiterated the concept and described mental processes and steps as including a list of descriptive mental terms, such as "determining," "comparing," and "observing."[50] A claim to the information of a specific DNA sequence, which correlates to the existence or absence of genetic susceptibility to a disease or other medical condition is similarly a claim to such a mental act and should be considered non-statutory subject matter.

Section IV considers recent developments in case law and USPTO practices which suggest that the patentability of the information of "isolated and purified" DNA sequences could and should be reconsidered. Although the case was not decided based on procedural grounds, the Court's consideration of the question of statutory subject matter in *Laboratory Corp. v. Metabolite, Inc.*,[51] the recent Federal Circuit cases of *In re Nuijten*,[52] *In re Comiskey*,[53] and *In re Bilski*,[54] as well as the Patent Office's clarification regarding the statutory nature of processes, all suggest a potential narrowing of the scope of patentable subject manner.[55] This development could have similar implications when considering the patentability of the intangible or embodied information of human DNA sequences under 35 U.S.C. § 101.

The Conclusion summarizes how the legality of patents on human genetic material could be challenged on this specific legal ground. When regarded as information, DNA sequences constitute non-statutory subject matter. Nevertheless, because of the confines of patent law, challenges to these patents are difficult and limited to infringers. Because they may also hold patents, it is arguable that potential plaintiffs will be reluctant to question the legality of the subject matter of a patent on the informational content of DNA and DNA sequences. This section also argues that the continued practice of patenting the informational content of human genetic material has possible Constitutional implications, as well as social, ethical, and policy concerns put forth by social scientists and philosophers who recognize that DNA is, in essence, information.

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49. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

50. *In re* Comiskey, 554 F.3d 967, 979-81 (Fed. Cir. 2009).

51. Lab. Corp. of Am. Holdings v. Metabolite Lab., Inc., 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting).

52. *In re* Nuijten, 500 F.3d 1346, 1352, 1357 (Fed. Cir. 2007).

53. *Comiskey*, 554 F.3d at 980.

54. *In re* Bilski, 545 F. 3d 943, 966 (Fed. Cir. 2008).

55. *See* Memorandum from John Love, Deputy Commissioner for Patent Examination Policy, to Technology Center Directors (May 15, 2008) (on file with author).

I. THE LAW, SCIENCE, AND LANGUAGE OF PATENTS ON HUMAN GENETIC INFORMATION

The United States Constitution grants Congress broad power to create laws in order "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."[56] These Congressional statutes are codified in the 1952 Patent Act, found in Title 35 of the United States Code, which includes various sections describing the requirements for obtaining patent protection.[57] The USPTO is the Department of Commerce's patent-issuing agency.[58] In addition to issuing patents, the USPTO administers patent laws through its Board of Patent Appeals and Interferences (Board).[59] Actions regarding patent infringement are heard by federal district courts, appeals of which are reviewed by the Federal Circuit Court of Appeals.[60]

The focus of this Article is § 101 of Title 35, which specifies and defines the subject matter for which patents may be obtained. Under § 101, a person who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[61] Courts have interpreted the nature of patentable subject matter, delineating exceptions to the section's general definition as well as clarifying the designated statutory categories.

The § 101 descriptions, "new and useful," have traditionally been distinguished by courts defining patentable subject matter from specific requirements regarding an invention's "utility" according to § 101 (broadly, the invention achieves a practical result) or of "novelty" delineated in § 102 (broadly, the invention has not previously existed within references considered and known as the "prior art").[62] Additional key sections of the title include § 103, described as "nonobviousness" (broadly, when comparing the prior art and the

56. U.S.CONST. art. I, § 8, cl. 8.

57. *See* 35 U.S.C. ch. 10 (2000).

58. USPTO, General Information Concerning Patents: Functions of the United States Patent and Trademark Office, http://www.uspto.gov/web/offices/pac/doc/general/index.html (last visited Feb. 15, 2009).

59. *See id.*

60. *See* 28 U.S.C. §§ 1295, 1400 (2000).

61. 35 U.S.C. § 101 (2000).

62. 35 U.S.C. § 102 (2000); *see* ROGER E. SCHECTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARKS 292, 315, 323 (2003).

claimed invention, the subject matter as a whole is not obvious to a person with ordinary skill in the art pertaining to the subject matter of the invention), and § 112, which includes the elements of enablement and written description (broadly, requirements of how the claims must be written, in order to enable their use and to establish, at the time the application was filed, the inventor had possession of the claimed subject matter).[63]

The Utility Examination Guidelines issued by the USPTO seek to provide guidance regarding the patentability of human genetic material, stating that DNA sequences are eligible for patent protection when "isolated from their natural state and purified, and when the application meets the requisite statutory criteria."[64] The Guidelines further provide that a purified and isolated DNA molecule, which is new and useful, is patentable; however the sequence information describing the compound alone is non-statutory.[65] Then Director of the Biotechnology Examination Technology Center at the USPTO (and now Deputy Commissioner), John Doll, wrote in May 1998 that a patent application for a DNA sequence must be distinguished from its nonpatentable naturally-occurring counterpart, in that the "patent application must state that the invention has been purified or isolated or is part of a recombinant molecule or is now part of a vector."[66]

This argument, that the informational content of genetic material that has been taken from its human source is somehow substantially different from its configuration as it exists in nature, is at first glance deceptively persuasive. The technological processes which allow for the informational content of genetic materials in the human body to be identified, i.e., "isolated" and "purified," are extremely complex. They are significant achievements rendering these basic biological materials useful. Nonetheless, a thorough examination of the types of sequences that are actually being claimed and the manner in which they are claimed fails to establish any meaningful distinctions under the law. Instead, it reveals only an abstraction, a construct: "Thus stripped of its identity as 'natural,' the unencumbered gene becomes readily susceptible to the creation and layering upon it of a new legal identity as 'man-made' through scientific interventions."[67]

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63. *See* SCHECTER & THOMAS, *supra* note 62, at 369, 394, 398.

64. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

65. *Id.*

66. John J. Doll, *The Patenting of DNA*, SCIENCE, Apr. 3, 1998, at 689.

67. Jonathan Kahn, *What's the Use? Law and Authority in Patenting Human Genetic Material*, 14 STAN. L. & POL'Y REV. 417, 426 (2003).

The informational content of "isolated and purified" human DNA molecules, the actual basis of the claim, is indistinguishable from the information as it exists in the natural environment. The information reflects and represents the same inherent characteristics and qualities of naturally-occurring human genes and DNA sequences, and has the ability to dictate and perform the same essential function of human genes found in nature–the capacity to code for proteins. In fact, the processes defined as isolation and purification used to extract the DNA from its natural source is only done for the very purpose of obtaining the information necessary for performing these exact and precise functions. Thus, in order to determine whether the processes involved in the removal of this information from the human body produces the required differentia to render it statutory subject matter, it is necessary to examine the composition of human genetic material and its functions, as well as the precise claims of the subject matter of the potential patent. A description of the science is important for an understanding of exactly what comprises the sequences being claimed.[68]

"The entire collection of genetic material of a particular organism is known as its 'genome.' Each cell of an organism contains a copy of the same genome, in the form of a set of structures called 'chromosomes,' which are made up of DNA."[69] DNA (deoxyribonucleic acid) is a long molecule found in each cell of every living organism; it consists of two strands, each made from smaller subunit molecules called nucleotides. These consist of a sugar (deoxyribose, or D); a phosphate, and a base. There are four types of bases: adenine (A), thymine (T), cystine (C), and guanine (G). In a DNA molecule, each base has its unique complement: an A on one strand is always paired with a T on the other, and a C is always paired with a G on the other.[70] These complementary bases are joined by weak hydrogen bonds, a process known as hybridization.[71] This weakness allows strands of DNA to be separated and put back

68. In discussing the nature of DNA as patentable subject manner, legal commentators have delineated the basic science. *See, e.g.*, Andrew Chin, *Research in the Shadow of DNA Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 846, 848-50 (2005); John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 301, 309-12 (2003).

69. Chin, *supra* note 68, at 848.

70. *Id.* at 848-49

71. Conley & Makowski, *supra* note 68 at 310 (citing GEORGE B. JOHNSON, THE LIVING WORLD 142 (1997)).

together. Thus the DNA strands are flexible, similar to a rope ladder or winding staircase visualized as the "double helix."[72]

"The order of bases in one strand of a DNA molecule is referred to as a molecule's 'structural formula,' 'nucleotide sequence,' or 'DNA sequence.' [DNA sequence] is also sometimes used to refer to a DNA molecule itself."[73] Thus,

> The genome consists of the sequencing of the four bases–A, T, C and G. The sequencing of the bases is the medium through which DNA stores and ultimately transmits information. The arrangement of these four bases . . . determines the nature, functionality, and often the health of an organism. In this respect the genome resembles a computer. Both can store enormous amounts of information by the almost endless repetition of very simple operations. In the case of the computer, the operation is binary. . . . In the case of the [human] genome, it is a four-way choice . . . repeated over and over, 3 billion times in the human genome.[74]

However, some regions of the human genome have a specific purpose, they are called genes, whose main function is to make proteins, the process of which is known as gene expression.[75] "DNA provides the template and control mechanisms for making these proteins."[76]

The making of proteins involves two steps known as transcription and translation.[77] Although DNA contains the information required to build the protein, the copying and carrying of that information to where it is needed is done by a related molecule, RNA (ribonucleic acid), also made up of nucleotides; differing from DNA, it has only one strand, is comprised of a different sugar, and has a base U, uracil, instead of T, thymine.[78] During transcription, the strands of DNA separate in the region containing the gene for that

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72. *Id.* (citing JOHNSON, *supra* note 71, at 141).

73. Chin, *supra* note 68, at 849 (citing Oak Ridge National Laboratory, *Genome Glossary* http://www.ornl.gov/TechResources/Human_Genome/glossary (last visited June 17, 2002) ("[D]efining DNA sequence as 'The relative order of base pairs, whether in a DNA fragment, gene, chromosome, or an entire genome.'"); U.S. Patent No 5,935,837, claim 13 (filed July 28, 1997) (showing the usage of "the language '[a]n isolated and purified DNA sequence' to claim an isolated and purified DNA molecule")).

74. *Id.* (citing *Symposium on Bioinformatics and Intellectual Property Law*, 8 B.U. J. SCI. & TECH. 190, 196 (2002)).

75. *Id.* at 310-11 (citing HARVEY LODISH ET AL., MOLECULAR CELL BIOLOGY 114 (4th ed. 2000)).

76. *Id.* at 311 (citing LODISH ET AL., *supra* note 75, at 111).

77. *Id.* (citing JOHNSON, *supra* note 71, at 143-46).

78. *Id.* (citing JOHNSON, *supra* note 71, at 143; LODISH ET AL., *supra* note 75, at 109).

protein.[79] Nucleotides of RNA match up with one strand of DNA, their complementary strand, so "an RNA C binds to a G on the DNA strand, an RNA G binds to a DNA C, and RNA U (the RNA version of T) binds to a DNA A, and an RNA A to a DNA T."[80] This creates a strand of RNA called "messenger RNA" (mRNA), whose "code is the complement of that on the template strand of DNA."[81]

Not all the DNA in a gene actually codes for proteins.[82] "Introns" are the non-coding regions lying between the coding regions, "exons." [83] As the primary mRNA strand (transcript) "is an exact complement of the template DNA, it contains both the introns and exons."[84] Introns are excised in a process called 'splicing,' which produces mature mRNA, containing only the coding regions, which then leaves the nucleus of the cell and enters the cytoplasm.[85]

Once in the cytoplasm, the second step of protein production begins as:

> The code transcribed on the mRNA is translated into a protein with the help of another type of RNA, transfer RNA or tRNA. The critical functional element in translation is the codon, a sequence of three nucleotides on the mRNA that specifies, or codes for, a particular amino acid. . . . Each unit of tRNA carries one of the twenty amino acids that are the building blocks, as well as a three nucleotide sequence (an anticodon) that is the complement of the mRNA code for its amino acid.[86]

Complexed with a ribosome, tRNA (with an anticodon),

> binds to its complementary mRNA codon, thereby bringing the specified amino acid into place. [As] this process continues, . . . [a]djacent amino acids are joined by chemical links called peptide bonds. . . . This chain of amino acids in a specific sequence forms a protein, or polypeptide. [87]

Thus, genes are now described as,

> "the entire nucleic acid sequence that is necessary for the synthesis of a functional polypeptide or RNA molecule." In addition to the coding regions making up the sequence of amino acids to build a

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79. *Id.* (citing LODISH ET AL., *supra* note 75, at 116)

80. *Id.* (citing JOHNSON, *supra* note 71, at 143).

81. *Id.* (citing JOHNSON, *supra* note 71, at 143).

82. *Id.* at 312.

83. *Id.* (citing LODISH ET AL., *supra* note 75, at 115).

84. *Id.* at 312.

85. *Id.* (citing LODISH ET AL., *supra* note 75, at 115-16).

86. *Id.* (citing JOHNSON, *supra* note 71, at 145-46) (citations omitted).

87. *Id.* at 313 (citing NEIL A. CAMPBELL ET AL., BIOLOGY 184-85 (1994); JOHNSON, *supra* note 71, at 145-46) (citations omitted).

> protein, it also contains the regions that code for tRNA and rRNA which make up the ribosome, the regions that control the beginning of the transcription process, and the regions that regulate the splicing of the primary mRNA transcripts.[88]

The first case to deal with the generic subject of human genetic material, *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[89] described the process known as "isolation and purification" used by scientists to identify any particular sequence or sequence fragment of human DNA. The case described "cloning a gene" as obtaining or "isolating" the portion of the double helix which contains the DNA sequence that the cell uses to create a particular protein, and pulling it out, extracting or "purifying" it."[90]

Patent claims covering this "isolated and purified" human genetic material can be a simple claim for the identified sequence. The following example is one of numerous claims to the specific genes involved in breast and ovarian cancer: "1. An isolated DNA coding for a BRCA-1 polypeptide [protein], said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2."[91] According to the definition provided in the patent, "isolated" is synonymous with "substantially pure," denoting "a nucleic acid . . . which is substantially separated from other cellular components which naturally accompany a native human sequence."[92] Thus, the "separated" nucleic acid is clearly identical in all respects to the naturally-occurring nucleic acid. Its informational content, the subject of the claim, is also identical.

These isolation and purification techniques have rapidly progressed, and continue to do so.[93] Prior to 1983, what were known as DNA libraries (dDNA), pools of a solution containing a set of all of the DNA sequences comprising all the genes found in our body's cells, were screened by biologists.[94] In addition, techniques were developed to make "libraries" of complementary DNA (cDNA). A cDNA molecule was simply a replication of the information contained within a molecule of messenger mRNA, using an enzyme

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88. *Id.* (citing LODISH ET AL., *supra* note 75, at 295) (citations omitted).

89. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied sub nom*. Genetic Inst., Inc. v. Amgen, Inc., 502 U.S. 856 (1991).

90. *Id.* at 1208.

91. U.S. Patent No. 5,747,282 col. 154 ll. 56-58 (filed June 7, 1995).

92. *Id.* at col. 19 ll. 8-12.

93. *See supra* notes 14-19 and accompanying text.

94. Amgen, Inc. v. Chugai Pharm. Co., No. 87-2617-Y, 1989 WL 169006, at *7-8 (D. Mass. Dec. 11, 1989).

in a test tube to reproduce the identical information.[95] As described in *Amgen*, short sequences of nucleotides called oligonucleotide probes are used to screen the libraries and isolate the genes by a complex series of steps.[96] An example of a claim to a cDNA molecule is as follows: "1. An isolated polypeptide comprising: . . . (c) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 209957."[97] A DNA sequence, however, broadly describes not just the informational content of the DNA, but of the mRNA as well, which in turn can be used as a template for cDNA synthesis. The information contained within the mRNA in its naturally-occurring state is, for purposes of the patent, identical to the information contained within this newly synthesized cDNA.

By 2000, scientists recognized the need to isolate DNA sequences from its human source, such as blood or other tissue samples, in a method that was computerized and affordable.[98] Described as "fully automatic high-throughput" instruments, the initial prototype allowed for the "purification of human blood or bacterial DNA in as little as 24 minutes."[99] A recent example of this new type of claim covers "polynucleotides encoding a human G-protein coupled receptor, HGPRBMY39."[100] Claim 1 is for:

> 1. An isolated nucleic acid molecule consisting of a polynucleotide sequence selected from the group consisting of:
>
> (a) an isolated polynucleotide encoding a polypeptide consisting of amino acids 1 to 370 of SEQ ID NO:2; and
>
> (b) an isolated polynucleotide encoding a polypeptide consisting of amino acids 2 to 370 of SEQ ID NO:2.[101]

Despite the advanced techniques utilized, it is still the sequence, the informational content, that is the essence of what is being claimed, and it is identical to that which existed in the human source.

The identification and isolation of the DNA sequence from its human source is the starting point, the primary basis as a new

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95. *Id.* at *8.

96. *See id.* at *8-10 (describing the screening process).

97. U.S. Patent No. 7,294,690 col. 455 ll. 20-31 (filed May 2, 2002).

98. Brian Bauman et al., *Automated, Low Cost Isolation of Blood or Bacterial Genomic DNA,* RESEARCH ABSTRACTS FROM THE DOE HUMAN GENOME PROGRAM CONTRACTOR-GRANTEE WORKSHOP VIII (2000), http://www.ornl.gov/sci/techresources/Human_Genome/publicat/00santa/42.html.

99. *Id.*

100. U.S. Patent No. 7,198,912 (filed Sept. 6, 2002).

101. '912 Patent, at col. 297 ll. 9-17.

molecular diagnostic tool for infection, genetic diseases, inherited traits, identity determination, and other research applications. Claims are made on DNA sequences known as SNPs (single nucleotide polymorphisms), DNA sequence variations that occur when a single nucleotide (A, T, C, or G) in the genome is altered. For a variation to be considered a SNP, it must occur in at least 1% of the population. In a patent application for a susceptibility gene for obesity and Type II diabetes, Claim 3 recites:

> 3. An isolated polynucleotide encoding a polypeptide having an amino acid sequence of a β3-adrenergic receptor having a substitution at amino acid residue 64 of arginine for trytophan and wherein the substituted receptor is associated with having or at risk of having an increased likelihood for developing Type II diabetes mellitus and/or obesity.[102]

Thus, like other similar claims on naturally occurring DNA sequences that have been isolated or removed from their natural environment, the sequence of a SNP is identical to one occurring in an individuals' DNA inside the body. If it varied in any way from its naturally occurring form, it would not be useful as an identifier of a variation in the general population.

Researchers involved in biotechnology do not simply claim only the isolated DNA sequences or SNPs, but routinely, the isolated sequence is the first claim in a series of claims for methods and processes which correlate the existence of the sequence or SNP in an individual's sample to the existence of a genetic susceptibility to a particular disease. Examples include the claims to genes, such as BRCA, relevant to breast and ovarian cancer. Claim 1 is: "1. An isolated consensus DNA sequence of the BRCA1 coding sequence as set forth in SEQ ID NO: 1."[103]

Claim 2 is:

> 2. A method of identifying individuals having a BRCA1 gene with a BRCA1 coding sequence not associated with breast or ovarian cancer comprising:
>
> a) amplifying a DNA fragment of an individual's BRCA1 coding sequence using an oligonucleotide primer which specifically hybridizes to sequences within the gene;
>
> b) sequencing said amplified fragment by dideoxy sequencing;
>
> c) repeating steps (a) and (b) until said individual's BRCA1 coding sequence is completely sequenced;

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102. U.S. Patent No. 5,766,851 col. 33 ll. 22-27 (filed May 19, 2002).

103. U.S. Patent No. 5,654,155 col. 65 ll. 44-45 (filed Feb. 12, 1996).

> d) comparing the sequence of said amplified DNA to the sequence of SEQ ID NO. 1;
>
> e) determining the presence or absence of each of the following polymorphic variations in said individual's BRCA1 coding sequence. . . ;
>
> f) determining any sequence differences between said individual's BRCA1 coding sequences and SEQ. ID. NO:1 wherein the presence of any of the said polymorphic variations and the absence of a polymorphism outside of positions 2201, 2430, 2731, 3232, 3667, 4427, and 4956, is correlated with an absence of increased genetic susceptibility to breast or ovarian cancer resulting from a BRCA1 mutation in the BRCA1 coding sequence.[104]

In the preceding series of claims, Claim 1 is simply directed to the identified and isolated sequence that represents or refers to the mutation within the specific gene. In such a state, the sequential information is fundamentally identical to what exists in nature; it exhibits no substantial sequence differences and its function in the body, to code for a protein, is identical to the uses for which the information is being patented.

Claim 2 covers the amplification of DNA fragments that collectively constitute a particular individual's BRCA1 gene and the subsequent sequencing of these DNA fragments. This is essentially the identification of an individuals' naturally-occurring BRCA1 gene sequence. The informational content of the sequences representing the arrangement or ordering of chemical bases is necessarily identical whether inside the individual's body or isolated in a test tube. Similarly, the function of this information is identical. The presence or absence of specific polymorphic variations correlates to susceptibility to breast or ovarian cancers. Therefore, if these isolated sequences of extricated information were not identical, they would be useless and perhaps dangerous, rendering them diagnostically imprecise.

Thus, considering the basic scientific knowledge regarding the structure of DNA and DNA sequences, as well as the precise nature of what is actually being claimed, a consistent principle emerges when assessing the statutory nature of human genetic sequences. Claims cover the information, the inherent knowledge revealed in the identified genetic sequence, and although the various processes that facilitate this identification might themselves be suitable subject matter, the revealed, identified, isolated, purified and/or replicated

104. *Id.* at col. 65 l. 46-col. 66 l. 54.

information is identical to that contained within its human source and is outside the scope of suitable subject matter for the grant of a patent.

II: LAWS OF NATURE AND HUMAN DNA SEQUENCES.

The Court has recognized limits to patentable subject matter under § 101. As stated in the 1981 Supreme Court case *Diamond v. Diehr*,[105] "every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomenon and abstract ideas."[106] The Court has given examples of such exclusions, including Newton's law of Gravitation describing the gravitational force between two objects as a function of their distance and mass,[107] Einstein's law for the inter-conversion of energy and mass,[108] the formula for determining the circumference of a circle,[109] the Arrhenius equation,[110] and the multiplication tables.[111] According to the Court, these laws reveal "a relationship that has always existed."[112]

Scientific principles, including their mathematical expressions, are synonymous with the excluded category.[113] Ideas and abstract concepts, which are the necessary basis for scientific and technological work, are similarly non-patentable.[114] The Court recognizes that these eternal laws of nature, even if recently discovered, should be universally accessible rather than exclusively possessed, and ruled that Congress should not privatize these natural laws; rather they should remain in the public domain.[115]

A well known case exemplifies the laws of nature doctrine. In the 1853 case *O'Reilly v. Morse*,[116] in considering the patenting of the invented telegraph, the Court questioned whether the underlying principle of electro-magnetism became similarly patentable when contained within a patentable process involving the new and useful

105. Diamond v. Diehr, 450 U.S. 175 (1981).

106. *Id.* at 185.

107. Parker v. Flook, 437 U.S. 584, 593 n.15 (1978).

108. Diamond v. Chakrabarty, 447 U. S. 303, 309 (1980).

109. *Flook*, 437 U.S. at 595.

110. *Diehr*, 450 U.S. at 188.

111. *Flook*, 437 U.S. at 598 (Stewart, J., dissenting).

112. *Flook*, 437 U.S. at 593 n.15.

113. *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

114. *Id.* at 67.

115. *In re* Meyer, 688 F.2d 789, 795 (C.C.P.A. 1982) (citing Le Roy v. Tatham, 55 U.S. (14 How.) 156, at 175 (1852)); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); Graham v. John Deere Co., 383 U.S. 1, 6 (1965).

116. O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).

application of the principle.[117] Claim eight of the patent stated that Morse was not claiming the specific machinery, but rather "the motive power of the electric or galvanic current."[118] The Court found this claim an unpatentable scientific principle, electromagnetism itself, as opposed to its creation by a process or machinery.[119]

The Court reiterated the concepts underlying the doctrine that laws of nature are not suitable subject matter for the grant of a patent. Describing the claim as too broad, it would give Morse exclusive rights to every such use of electromagnetism, including those to subsequent inventions that he himself did not create. It would deter innovation and deprive the public of the benefits of those possible new inventions.[120]

The genetic code is similarly illustrative of a fixed relationship which is universal and timeless: the translation of the DNA sequence to produce proteins. Accordingly, the genetic code is a law of nature. Just as the grant of a patent in *Morse* for all uses of the principle of electromagnetism would have given exclusive rights to all uses of the principle, the grant of a patent to the information in a specific DNA sequence restricts public access to the genetic code itself, a law of nature, when the instructions contained within that DNA for assembling amino acids into a specific protein are excluded from use. Thus, patents on the information contained within DNA sequences, whether existing in their natural environment or having been isolated, purified, or replicated, are not statutory subject matter.

Similarly, the innate, pre-existing information of isolated human DNA is also a scientific principle, as opposed to any process or machine for identifying or replicating a segment of human DNA. They are expressions of the same basic scientific principles and truths, the scientific information existing in DNA and DNA sequences within the human body. Although the information of human genetic material is either intangible information contained within a molecule or can be considered information materialized or embodied in a molecule, it is the intangible information for which the patent is being sought, whether existing in its natural environment or having been identified, isolated, purified, or replicated. Without the inclusion of the innate information, the molecule is irrelevant for a patent claim. Alternatively, it is arguable that the claimed molecule is actually the embodied information itself; it is the precise *arrangement* of chemical

117. *Id.*
118. *Id.* at 112.
119. *Id.* at 120.
120. *See id.* at 113.

base pairs being sought. One cannot patent the physical entity without claiming the scientific relationship the genetic material represents or deciphers in its natural state.[121]

This genetic information is a basic tool of scientific and technological work, and exclusive rights to its use should not be granted. Doing so removes this age old knowledge from the public domain. Just as Morse's claim to all uses of electromagnetism was denied patent protection for these justifications, the potential to deter innovation and deprive the public the benefits of possible inventions, patents on the informational content of DNA sequences should not be granted.

Thus, various claims to human DNA sequences, whether or not they have been identified, isolated, purified, or replicated is a manifestation of a law of nature. As information, it is an expression of an idea, a pre-existing scientific truth or principle and ultimately a research tool, and represents an express limitation on statutory subject matter.

A. Representations of Base Pairs as Reading on the Information Itself

A recent Federal Circuit decision, *In re Nuijten*,[122] questioned whether a patent claim for intangible information falls into any of the enumerated categories of statutory subject matter.[123] The court considered whether "transitory electrical and electromagnetic signals propagating through some medium, such as wires, air, or a vacuum,"[124] were encompassed by the enumerated categories of 35 U.S.C. § 101: "process, machine, manufacture, or composition of matter."[125] The claimed invention was directed to a technique for improved "watermarking," a technology whereby an original signal (such as a digital audio file) is embedded or encoded with additional data. The claimed technique improved the technology by further modifying the watermarked signal, compensating for the distortion caused by the watermark.[126]

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121. *See* GLOBAL GENOME, *supra* note 6, at 20 ("However, the key to understanding the complexities of genetics and biotechnology is in the realization of a paradox at the core of the concept of biological exchange: that biology is information, and, crucially, that information is both material and immaterial.").

122. *In re* Nuijten, 500 F.3d 1346, 1353 (Fed. Cir. 2007).

123. *Id.*

124. *Id.* at 1352.

125. 35 U.S.C. § 101 (2000).

126. *In re Nuijten*, 500 F.3d at 1348-49.

The court noted that the process claims of the invention were proper subject matter for a grant of a patent, as were "any apparatus for generating, receiving, processing or storing the signals," but the claims on appeal sought to cover only the resulting encoded signals.[127] Claim 14 reads: "A signal with embedded supplemental data, the signal being encoded in accordance with a given encoding process and selected samples of the signal representing the supplemental data, and at least one of the samples preceding the selected samples is different from the sample corresponding to the given encoding process."[128] The Board affirmed rejections of Claim 14: they reasoned that the claim was an unpatentable abstract idea as the signal had no physical attributes, and the claimed signal was not within any of the four categories of statutory subject matter.[129]

The court first examined the issue of how the claim was constructed, recognizing that statutory subject matter is an issue of both claim and statutory construction.[130] The determination would be based upon whether the claims were limited to covering only "physical" instances of the signals, or if they also covered the disembodied, numerical information of the signal itself.[131] While agreeing with Nuijten's argument that the signal must be in some physical form in order to be perceived, the court stated that as long as a recipient could understand the message of a signal, the form or type of the signal's physical carrier was irrelevant to the disputed claims.[132] Even though the claims required physical substance, the specific nature of the carrier was not delineated. Thus, the court reiterated that Claim 14 was simply for the signal's informational content, and was therefore non-statutory subject matter.[133]

Specific patent claims to DNA sequences illustrate that, like Nuijten's signal, the only limitations in these claims address the informational content of the DNA being claimed. DNA is a nucleic acid containing four bases, A, C, G, and T, "appear[ing] in a linear array along the DNA molecule."[134] A DNA sequence is a unique arrangement of those bases, like a correctly spelled word using the

127. *Id.* at 1351.

128. *Id.* (emphasis omitted).

129. *Id.* at 1351-52.

130. *Id.* at 1352 (citing State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1370 (Fed. Cir. 1998)).

131. *Id.* at 1353.

132. *Id.*

133. *Id.*

134. Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 708 (2004).

right arrangement of letters.[135] However, the nature of DNA is not just one of a static chemical compound, but also functions as a dynamic template, with the embodied information specifying instructions for synthesizing a specific protein.[136] Described by geneticist Dr. Max Perutz:

> The structure of DNA gave to the concept of the gene a physical and chemical meaning by which all its properties can be interpreted. Most important, DNA—right there in the physical facts of its structure—is both autocatalytic and heterocatalytic. That is, genes have the dual function, to dictate the construction of more DNA, identical to themselves, and to dictate the construction of proteins very different from themselves.[137]

This basic nature and function of DNA is exemplified in the previously examined BRCA patents, all of which claim a simple coding sequence. Like the signal in *Nuijten*, they are simply being claimed for the facts of their structure. Although this recitation of an order of chemical base pairs is embodied, it is nonetheless being claimed for the ability to instruct the building of identical DNA or proteins, its use as the disembodied arrangement of the chemical bases. These claims thus read on the sequences which have been identified as the genes associated with breast cancer. It is patented information, the unauthorized use of which is an act of infringement. A described claim, although once embodied as a molecular structure, is also information representative of that structure; a formula describing what a particular DNA sequence codes. It is a set of instructions for how the protein is synthesized when the DNA template is decoded into RNA by enzymes in the cell, and the subsequent decoding of the RNA into protein.

Similarly, on a patent claim for the SNP suggesting susceptibility to obesity and type II diabetes mellitus, the essence of the claim seeks to patent the pure information revealed in the claimed sequence. The only limitation of this claim, like the signal in *Nuijten*, reads on its informational content: in essence, the pure information itself is the actual basis for the claim. A proper construction of the claim asks whether, like the signal, the isolated sequence encoding for a protein with certain substitutions, these substitutions representing a variation

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135. *See id.* 708, 709 n.4 (quoting Dr. Marshall Nirenberg, The Genetic Code, Nobel Lecture (Dec. 12, 1968), *in* NOBEL LECTURES IN PHYSIOLOGY OR MEDICINE: 1963-1970, AT 372, 390 (1972)).

136. *Id.* at 712.

137. *Id.* at 710 n.11 (quoting Dr. Max Perutz *in* HORACE FREELAND JUDSON, THE EIGHTH DAY OF CREATION: MAKERS OF THE REVOLUTION IN BIOLOGY 7 (expanded ed. 1996)).

within the information of the sequence associated with Type II diabetes or obesity, is limited to the tangible material of the isolated polynucleotide. Or, if the claims also cover the intangible ordering of abstract numbers, merely unencumbered numerical information.

Analogous to the signal at issue in *Nuijten*, the isolated polynucleotide encoding for the protein has physical substance, but like the claim for the signal, the claim for the isolated polynucleotide does not specifically reference its "carrier element." Rather it is the sequence itself, the "merely numerical information" representing the order of the chemical bases which is the essence of the claim. In fact, the use of the term "isolated" can also suggest that its "carrier element" is of no import in the construction of the claim; the information having been identified and "extricated" from the carrier molecule. The important element, like the signal, is the fact that "a recipient can understand the message." The specific type or form of its physical carrier, i.e., the molecule, is totally irrelevant to the claim.[138]

As with the signal, the only meaningful consideration is the recipient's ability to comprehend the message contained within the information, the representation of an arrangement of base pairs. Patent claims on these sequences "read on the information" itself. Like similar expressions of mathematical formulas, algorithms, scientific principles and laws of nature, this informational content does not constitute statutory subject matter.

B. Patents that Preempt Preexisting Scientific Principles

The metaphoric relationship between computer and information technologies and human genetics has been examined by scientists, social scientists, and philosophers of science.[139] Comparing the expression of a gene to a mathematical algorithm such as those involved in the writing of computer software programs suggests that the purely informative nature of genetic sequences are synonymous to the codes of computer software. The cellular machinery is the hardware executing either naturally occurring or technologically produced software, the genetic code encrypted in the DNA.[140]

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138. *See In re* Nuijten, 500 F.3d 1346, 1353 (Fed. Cir. 2007).

139. *See supra* notes 1-10 and accompanying text.

140. *See, e.g.*, Mark Christopher Farrell, *Designer DNA for Humans: Biotech Patent Law Made Interesting for the Average Lawyer*, 35 GONZ. L. REV. 515, 532 (1999-2000) (citing Milagros del Corral, *Legal Aspects of Genome Protection*, *in* 2 THE HUMAN GENOME PROJECT: LEGAL ASPECTS 227, 230 (Fundación BBV ed., Larry Lilue trans., 1994)).

Similarly, the "information processing" system implemented by the workings of genetic sequences is analogous to the workings involved in computer technology systems.[141] Both systems encode information used in controlling and directing either the biological processes, the workings of a cell, or of a computer system.[142] The instructions and data of nucleotide sequences are encoded and stored in biological containers.[143] Specific binary encoded sequences of electrical, magnetic, or optical data are stored in a computer system.[144] Both produce informational outputs when the instructions have been executed or when data is accessed: messenger RNA in the case of human genetic material and, e.g., communication signals in computer technology.[145]

The Report discussed above acknowledges DNA sequences as patented for their informational content and asserts that the analogous nature of human genetics and computer technologies might provide guidance in a challenge to the validity of patents issued to human genes.[146] The Report noted that:

> Older cases have excluded from patent protection "scientific truths" and "abstract ideas." The sequence of genomes, the identification of polymorphisms and haplotypes, the development of gene expression profiles, and the determination of protein structures all provide valuable scientific information that arguably falls within these exclusions . . . if the patent claims read beyond the materials themselves and attempt to define the invention in such a way that the use of information would be an act of patent infringement. Recent decisions concerning the patentability of computer-implemented inventions may provide more guidance than prior decisions about the patentability of discoveries in the life sciences and in predicting the patentability of informational inventions in genomics and proteomics.[147]

Claims to previously described types of isolated and purified DNA and DNA sequences are claims to information independent of its physical source which, when used by others than the patent-holders, are infringed. Contemporary cases dealing with algorithms in computer technology have further delineated the laws of nature

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141. *See* Brief for Houston Intellectual Prop. Law Ass'n as Amici Curiae Urging Reversal, *In re* Beauregard, 53 F.3d 1583 (Fed. Cir. 1995) (No. 95-1054).

142. *Id.* at 3.

143. *See id.*

144. *Id.*

145. *Id.*

146. *See Report*, *supra* note 9, at 76-77.

147. *Id.* at 76-77 (citations omitted).

doctrine. They are analogous and will have precedential value if patents granted to the informational content of human genetic material are challenged.

In the 1972 case, *Gottschalk v. Benson*,[148] the Court questioned whether a method for converting numerical information from binary-coded decimal numbers into pure binary numbers for programming conventional, general purpose digital computers was a statutory process.[149] The Court noted that the claims were not for a specific device or machine or any resulting use. Rather, they claimed any use of the method in any computer or any type of general-purpose digital computer.[150] The Court described the claim as an algorithm, defined as "[a] procedure for solving a given mathematical problem" or "a generalized formulation for programs to solve mathematical problems."[151] The claims were merely variations on the ordinary arithmetic that could be performed by existing computers, as well as by a human without the aid of a computer.[152]

The Court recognized that "[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."[153] The Court held that the claimed invention was non-statutory subject matter and that granting a patent on a formula for converting the numbers would be a patent granted to the algorithm itself, the effect of which would totally preempt its use in any other application.[154]

In 1978, the Court in *Parker v. Flook*[155] considered whether a method for updating alarm limits during the process of catalytic conversion was suitable subject matter for the grant of a patent.[156] The method consisted of three steps: one which initially measured the temperature; a second which used an algorithm defined as "a procedure for solving a given type of mathematical program" to calculate a new value for an alarm limit, and a final "post solution" step that adjusts the alarm limit to the updated value.[157] The claims did not cover every possible application of the formula and the

148. Gottschalk v. Benson, 409 U.S. 63 (1972).
149. *Id.* at 64.
150. *Id.*
151. *Id.* at 65.
152. *See id.* at 67.
153. *Id.* (citing Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1852)).
154. *Id.* at 72.
155. Parker v. Flook, 437 U.S. 584 (1978).
156. *Id.* at 585.
157. *Id.* at 586 & n.1 (quoting *Gottschalk*, 409 U.S. at 65).

formula could be used outside the industry for which it was being applied.[158]

The Court relied upon *Benson* to determine whether the claimed process was within the scope of statutory subject matter.[159] Considering an algorithm a mathematical formula, an unpatentable law of nature, the Court ruled the process to be non-statutory.[160] *Parker* did not find that the lack of a total pre-emption of the formula or the "post-solution activity" of adjusting the alarm limit to the newly computed limit distinguished the case from *Benson*.[161] Rather, in determining whether the claimed process was within the scope of patentable subject matter, the Court stressed that the process itself must be new and useful.[162] An algorithm, as a basic scientific or technological tool, whether it was known or unknown at the time of the claimed invention, is treated as being within the prior art.[163] In *Parker*, the scientific principle was well known and not entitled to a patent.[164]

The Court stated that one could not simply add the description of a practical application of an abstract idea to make it patentable. If this were the case, the determination of statutory subject matter would rely on how the claim was drafted, contrary to the principles regarding the inability to patent ideas or laws of nature.[165] Since all other features of the invention were not new, including the use of computers for "automatic monitoring-alarming," the Court described the claim as simply a new and, perhaps, improved method for calculating the values.[166] Thus, *Parker* held that "if a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory."[167]

The Court noted that a law of nature was not the type of invention for which the statute was enacted.[168] A footnote in the case expounds upon the rationale: scientific principles such as the respondent's algorithm reveal permanent preexisting relationships and

158. *Parker*, 437 U.S. at 589-90.
159. *Id.*
160. *Id.* at 594.
161. *Id.* at 590.
162. *Id.* at 591.
163. *Id.* at 592.
164. *Id.* at 594.
165. *Id.* at 593.
166. *Id.* at 594-95.
167. *Id.* at 595 (quoting *In re* Richmond, 563 F.2d 1026, 1030 (C.C.P.A. 1977)).
168. *Id.* at 589.

their mere recognition should not be given exclusionary rights.[169] Patentable subject matter must be new or novel, not simply newly discovered. In granting patents, the public should not be denied rights it freely enjoyed in the past.[170]

The Court also noted that the patent claim must be considered in its entirety. The process is unpatentable subject matter not because it contains a mathematical algorithm, but because once the algorithm is designated as within the prior art, the entire claim is not an invention suitable for patenting. An inventive application of a well-known phenomenon of nature or mathematical formula may be patented; a patent, however, cannot be granted on its discovery unless the claim also contains another inventive concept.[171] Thus, because the algorithm, the law of nature, pre-existed the claimed invention, and because there were no other inventive concepts in its application, the process was considered non statutory.[172]

A case from the Federal Circuit, *In re Warmerdam*,[173] examined whether mathematical calculations performed with mathematical algorithms to generate a data structure was statutory subject matter.[174] The claimed invention was based upon technology called "bubble systems" used to avoid collisions between moving objects.[175] Objects to be avoided were treated as if they were circles or spheres large enough to be enclosed, assuming that any motion impinging on the circle would cause the collision.[176] The claim was merely directed to a refined technique called "bubble bursting," where the spherical bubble zone was replaced with a set of smaller zones if a collision were detected.[177] The claimed invention involved methods for generating a "data structure," which itself was not described, but which included the measured "dimensions and coordinates of the bubble hierarchy," and a machine which had a memory containing data that represented the bubble hierarchy.[178]

The claimed collision-avoidance technique involved an arranged hierarchy of bubbles along an object's medial axis, resulting in

169. *Id.* at 593 n.15.
170. *Id.*
171. *Id.* at 594.
172. *Id.*
173. *In re* Warmerdam, 33 F.3d 1354 (Fed. Cir. 1994).
174. *Id.* at 1355.
175. *Id.*
176. *Id.*
177. *Id.* at 1356.
178. *Id.* at 1355.

computational efficiency.[179] Claim 1 referred to a method for locating the medial axis of a shape and then creating the bubble hierarchy on the axis.[180] Claims 2-4 were for "top-down" and "bottom-up" procedures, including the use of mathematical algorithms, to create the hierarchies.[181] Claim 5 was for the machine, i.e., the computer with memory containing the data representing the hierarchy, and Claim 6 was for the data structure generated by the methods of claims 1-4.[182] The Board sustained the examiner's rejections of claims 1-6, noting that claims 1-4 and 6 were rejected as lacking statutory subject matter under 35 U.S.C. § 101.[183]

The Federal Circuit examined the function of the process and whether the process itself constitutes an abstract idea, natural phenomenon, or law of nature.[184] The two steps of Claim 1 involved solving a mathematical algorithm using a Hilditch Skeletization method.[185] Claims 2-4 were also mathematical in nature.[186] The court cited cases where process steps similar to the claims in 1-4, described as "computing," "determining," "cross-correlating," "comparing," "selecting," "initializing," "testing," "modifying," and "identifying" were found to implicitly recite the implementation of a mathematical algorithm.[187] Although recognizing that the method could be used without the algorithm, the issue was whether the claimed process went beyond manipulating abstract ideas or natural phenomenon.[188]

The court asserted that the claims of locating the axis and creating the hierarchy only described this basic manipulation, the paradigm of an abstract idea.[189] Rejecting the argument that the claim might also contain a physical measuring step, the court found this "indistinguishable from [a] data gathering step which . . . [is] insufficient, standing alone, to impart patentability" to claims 1-4.[190] The data structure of Claim 6 was considered to be "*physical or logical* relationships among data elements, designed to support

179. *Id.* at 1356-57.

180. *Id.* at 1357.

181. *See id.* at 1357-58.

182. *Id.* at 1358.

183. *Id.* (noting that Claim 6 was specifically rejected "on the ground[s] that a 'data structure' is not within one of the categories of patentable subject matter listed in § 101.")

184. *Id.* at 1359-60.

185. *Id.*

186. *Id.*

187. *Id.* at 1359 (citing *In re* Grams, 888 F.2d 835 (Fed. Cir. 1989); *In re* Meyer, 688 F.2d 789 (C.C.P.A. 1982); and *In re* Johnson, 589 F.2d 1070 (C.C.P.A. 1978)).

188. *Id.* at 1359.

189. *Id.*

190. *Id.* at 1360 (citing *Grams*, 888 F.2d at 840).

specific manipulation functions."[191] The claim was found to be "another way of describing the manipulation of the ideas contained [in the claimed process]" rather than a physical structure which arranged the contents of a memory, and was rejected by the court for lack of statutory subject matter.[192]

Like the claimed algorithms underlying the processes of *Benson*, human genetic sequences are similarly pre-existent scientific principles and laws of nature and thus non-statutory subject matter. Like the mathematical formula which converted numerical information, a DNA sequence is, in essence, an algorithm for the production of proteins. Where the algorithm in *Benson* "convert[ed] one form of numerical representation to another,"[193] the process of identifying, isolating, purifying, and replicating the information contained within DNA existing in its natural state into its identified state, similarly converts one form of numerical representation into another. The content of the information does not differ as a result of the conversion. Although newly identified or isolated, claimed genetic sequences represent relationships that are pre-existing scientific principles.

Like the non-statutory algorithm in *Benson*, there is nothing "new" in the intangible or embodied information of isolated DNA. Nor is there any claimed machine or apparatus implementing the information, it stands alone. As in *Benson*, where the claimed patent would wholly pre-empt the algorithm, patent rights to the use of this information wholly pre-empt its use. This occurs when the patent-holder of DNA or a DNA sequence excludes others from utilizing that particular sequence as a template to the information contained in the genetic code.

The algorithm in *Flook* was described solely as a process for solving a mathematical problem.[194] Similarly, claims to identified, isolated, purified DNA sequences do not contain "other inventive concepts."[195] Although it is arguable that these newly identified sequences are representative of a practical application of the information contained within human genetic material, they are nevertheless identical to those found in nature.

The addition of the description "isolated and purified" can be similarly seen as the work of a "competent draftsman . . . attach[ing]

191. *See id.* at 1362 (quoting IEEE, IEEE STANDARD COMPUTER DICTIONARY (1991)).

192. *Id.* at 1362.

193. Gottschalk v. Benson, 409 U.S. 63, 65 (1972).

194. *See* Parker v. Flook, 437 U.S. 584, 585 (1978).

195. *Id.* at 594.

some form of post-solution activity" to the algorithm represented by the instructions contained within the genetic sequence information.[196] Like the practical application of updating alarm limits in *Flook*, a gene in an isolated and purified form simply provides a new and better method for the identical calculations involved in the workings of genetic information. The practical application of the genetic information as a whole is directed to the use of a formula, the instructions for the synthesis of proteins through gene expression.

Although the process by which the information has been identified and isolated might be new, the information of a genetic sequence obtained by these processes is not new, but has pre-existed in the natural environment. The sequence, like the algorithm, existed before the invention was claimed.[197] Similar to the algorithm in *Flook*, the information is "within the prior art."[198] There are no other "inventive concepts" being claimed.

In *Warmerdam*, claims involving equations for solving the problems regarding the collision of objects were non-statutory. The step of physically measuring an object's contours was seen as a data gathering step insufficient to impart patentability when standing alone.[199] Similarly the process of identifying, isolating, purifying, and/or replicating the information of a DNA sequence, SNP, or cDNA results in a claim for the same information, what the court found objectionable as merely "a manipulat[ion] of 'abstract ideas' [and] 'natural phenomenon.'"[200]

Precision regarding the terminology was not required in examining whether the claims in *Warmerdam* implicitly recited the solving of a mathematical algorithm. Many terms were cited as representative of the basic underlying concept, including "identifying."[201] The terminology, "isolated and purified" represents nothing more than a manipulation of abstract, numerical information, which, in essence, is simply identifying and retrieving the natural phenomenon of the information in a DNA sequence. A physical measurement, or gathering of data, standing alone, was insufficient to have made the claims statutory in *Warmerdam*.[202] The isolation and purification process is nothing more than a similar data gathering

196. *Id.* at 590.
197. *See id.* at 594.
198. *Id.*
199. *In re* Warmerdam, 33 F.3d 1354, 1360 (Fed. Cir. 1994).
200. *Id.*
201. *Id.* at 1359.
202. *Id.* at 1360.

technique and does not impart patentability for claims to the innate information being claimed. Claims for the information of DNA sequences, like the claims in *Benson*, *Flook*, and *Warmerdam*, are similarly directed to non-statutory laws of nature.

C. The Transformative Nature of Process Claims

Subsequent decisions of the Court and lower courts regarding computer-related technologies have similar precedential value when considering patents on the informational content of human genetic material and whether they should be considered to claim non-statutory laws of nature.[203]

In *Diamond v. Diehr*,[204] the Court distinguished *Benson* and *Flook* while considering whether a process using a mathematical algorithm and a programmed digital computer in order to cure synthetic rubber was patentable subject matter.[205] The claimed invention improved upon the process of curing rubber by constantly measuring the temperature inside the mold and feeding those temperature measurements into a computer.[206] Using a mathematical formula, the Arrhenius equation, the computer would periodically recalculate the cure time.[207] When the recalculated time equaled the time when the press was closed, the computer sent a signal for the press to be opened.[208]

Unlike the claim in *Benson*, where the algorithm was used to convert numbers, or the claimed formula for computing an updated alarm limit in *Flook*, the Court found the respondents did not seek a patent on a mathematical formula.[209] "Instead they [sought] patent protection for a process of curing synthetic rubber. Their process admittedly employ[ed] a well-known mathematical equation, but they [did] not seek to pre-empt the use of that equation."[210] The respondents only claimed the use of that equation in conjunction with the other enumerated steps in their claimed process.[211] The Court maintained that,

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203. *See, e.g.*, Diamond v. Diehr, 450 U.S. 175 (1981); Gottschalk v. Benson, 409 U.S. 63 (1972); Parker v. Flook, 437 U.S. 584 (1978).

204. Diamond v. Diehr, 450 U.S. 175 (1981).

205. *Diehr*, 450 U.S. at 177.

206. *Id.* at 178-79.

207. *Id.*

208. *Id.*

209. *Id.* at 186-87.

210. *Id.* at 187.

211. *Id.*

> when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.[212]

Viewing the claim as drawn to a transformative industrial process for molding rubber, rather than an attempt to patent the underlying mathematical formula, the Court held that the process was statutory subject matter.[213]

The processes of identification, isolation, purification, and replication of naturally-occurring DNA sequences do not transform the retrieved information into something other than the information originally existing in its natural environment. A transformative step is required for patentability as illustrated by cases dealing with algorithms and computer technology. Where the Arrhenius equation in *Diehr* was implemented to produce cured rubber, the equation or principle involved in the recitation or replication of a DNA sequence, i.e., the formula, the abstract idea of the information contained within a gene, remains identical to the original equation or principle found in nature despite the techniques involved in the process of "isolation and purification." Thus, patent claims to this sequential information, unlike the process involved in *Diehr*, are not in any way transformative.

Claims were upheld following *Diehr* where transformations occurred.[214] In *In re Alappat*, the invention was for "a means for creating a smooth waveform display in a digital oscilloscope."[215] Claim 15 covered "[a] rasterizer for converting vector list data representing sample magnitudes of an input waveform into anti-aliased pixel illumination intensity data to be displayed on a display means" and was comprised of four steps.[216]

The court described the rasterizer of Claim 15 as a machine.[217] The court discussed cases such as *Flook*, noting that a process which employed a law of nature would be patentable even though such law

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212. *Id.* at 192.

213. *Id.* at 192-93.

214. *See, e.g.*, *In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994); State St. Bank & Trust v. Signature Fin. Group, 149 F.3d 1368, 1373 (Fed. Cir. 1998); AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352, 1359-60 (Fed. Cir. 1999).

215. *Alappat*, 33 F.3d at 1537.

216. *Id.* at 1538-39.

217. *Id.* at 1541

of nature would not.[218] A claim containing an algorithm within a process which transforms an article is statutory.[219] The means of Claim 15 represented circuitry elements that performed mathematical calculations, and the algorithms combined with these circuitry elements formed a machine which transformed the data samples into displayable intensity data.[220] This process was not an abstract idea, but a specific machine which produced a useful, concrete, and tangible result.[221]

The expansion of the scope of patentable subject matter was exemplified by the seminal 1998 Federal Circuit case *State Street Bank & Trust v. Signature Financial Group*.[222] The case examined whether a data processing system for implementing an investment structure for the administration and accounting of mutual funds was suitable subject matter for the grant of a patent.[223]

The system, known as "Hub and Spoke," implements a "structure whereby mutual funds (the Spokes) pool their assets in an investment portfolio (Hub) organized as a partnership."[224] The system "allows an administrator to monitor and record financial information flow and make all calculations necessary for maintaining a . . . financial services fund" for the members involved in the partnership.[225] Claim 1, covering the data processing system, was comprised of "means" including a computer processor, a data disk as the storage means and arithmetic logic circuits for storing and processing the data.[226] The court found that Claim 1 was for a machine which processed data for managing financial services.[227]

The court, relying on *Diehr*, found this machine patentable subject matter.[228] Abstract ideas became patentable when they were

218. *See, e.g.*, *id.* at 1542 n.18.

219. *Id.* at 1543 (citing Diamond v. Diehr, 450 U.S. 175, 192 (1981); *In re* Iwahashi, 888 F.2d 1370, 1375 (Fed. Cir. 1989); *In re* Taner, 681 F.2d 787, 789 (C.C.P.A. 1982)).

220. *Id.* at 1544.

221. *Id.* A recent decision from the Federal Circuit, *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), discussed *infra* at notes 254-277 and accompanying text, affirms the holding that the definitive test for patentability relies on the transformative nature of the claimed process, and that the "useful, concrete and tangible result" test, first "set forth in *Alappat*," is not the "appropriate inquiry." *See In re* Bilski, 545 F.3d at 959-60 (Fed. Cir. 2008).

222. State St. Bank & Trust v. Signature Fin. Group, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

223. *Id.* at 1370.

224. *Id.*

225. *Id.* at 1371.

226. *Id.* at 1371-72.

227. *Id.* at 1372.

228. *Id.* at 1373.

reduced to some type of practical application, i.e., "a useful, concrete and tangible result."[229] The court relied on *Alappat* for the proposition that the transformation of the wavelength data constituted an example of an abstract idea, like a mathematical algorithm, which had been practically applied.[230] Thus, the court held that this machine allowed for the transformation of data using a series of mathematical calculations to determine a final share price.[231] This constituted a practical application of the underlying mathematical principle (i.e., algorithm, formula, or calculation) and produced a result which was useful, concrete, and tangible–the final price was "momentarily fixed for record[ing] and reporting purposes and . . . relied upon by regulatory authorities."[232]

Relying on the rationale of *State Street*, the Federal Circuit, in *AT&T Corp. v. Excel Communications, Inc.*,[233] considered whether a claimed process for creating an indicator useful for billing purposes for long distance telephone calls was statutory subject matter.[234] The patent described a message record for long-distance telephone calls that is enhanced by adding a primary interexchange carrier (PIC) indicator. Within the system, Boolean algebraic principles applied to subscribers' and call recipients' carrier data determined the value of the data and applied that value through switching and recording mechanisms. The PIC indicator represents information about the call recipient's PIC, which the court described as a useful, concrete, tangible result: the ability of the interexchange carrier's calls to be differentially billed.[235]

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229. *Id.* (citing *In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994)). *Cf. In re* Bilski, 545 F.3d 943, 960 n.19 (Fed. Cir. 2008) (reaffirming the "machine or transformation test" and in a footnote stating: "As a result, those portions of our opinions in *State Street* and *AT&T* relying solely on a 'useful, concrete and tangible result' should no longer be relied upon.").

230. *State St.*, 149 F.3d at 1373. The court also referred to *Arrhythmia Research Tech., Inc. v. Corozonix Corp.*, 958 F.2d 1053, 1059 (Fed. Cir. 1992), where the transformation of electrocardiograph signals from a patient's heartbeat by a machine through a series of mathematical calculations constituted a practical application of an abstract idea because it corresponded to a useful, concrete, or tangible thing–the condition of a patient's heart. *Cf. In re Bilski*, 545 F.3d at 959-60 (discussing that the practical application of the abstract idea corresponding "to a useful, concrete, or tangible thing," is no longer the proper inquiry into the patentability of a process; instead, the proper question is whether the claimed process has a transformative effect).

231. *State St.*, 149 F.3d at 1373.

232. *Id. Cf. In re Bilski*, 545 F.3d at 960 n.19 (holding that the "useful, concrete, and tangible result" test should no longer be relied upon).

233. AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352 (Fed. Cir. 1999).

234. *Id.* at 1358.

235. *Id.* However, the "useful, concrete, and tangible result" test for subject matter patentability is no longer the sufficient inquiry for patentability. *See*, *In re Bilski*, 545 F.3d at 960 n.19.

The court relied upon *In re Alapatt* and *State Street* for the proposition that in order to patent an algorithm, its application must be useful, and held that, without preempting other uses of the mathematical principle, AT&T's Boolean principle was employed to produce a useful, concrete, and tangible result.[236] In finding the process transformative, the court also looked to *Arrhythmia*, where the claimed process was statutory because the algorithm produced a number with a specific meaning.[237] No longer an abstraction, the *Arrhythmia* algorithm's use produced a useful, concrete, and tangible result.[238]

The process of DNA "isolation and purification" does not transform the genetic information, the scientific principles or formulas of the recited claimed genetic sequences, into a different state or thing. Despite a potentially "useful, concrete, and tangible result" produced by isolating and purifying naturally-occurring DNA molecules, nothing is transformed by the process. Unlike the transformed underlying data of *In re Alapatt*, *State Street Bank*, and *AT&T*, the underlying data, i.e., the naturally-occurring sequence involved in the process, remains identical to the data produced as a result of the process. In both *State Street* and *AT&T*, it is arguable that with the aid of mathematical equations, simple underlying data and numerical information become transformed into numerical information imparting a different value to the information contained within the original data. Although the claimed isolated, purified, or replicated DNA sequence has a useful application, the initial data is identical and useful in a similar way, as instructions to code for protein. The sequence remains unchanged and untransformed, having the same essential and inherent value as the original information.[239]

Lower courts after *Diehr* expanded the patentability of algorithms embedded within process claims, but only when the process had a similarly transformative result. The 1994 Federal Circuit case *In Re Schrader*[240] involved a novel method for

236. *AT&T*, 172 F.3d at 1357-58 (citing *State St.*, 149 F.3d at1368, 1373; Arrhythmia Research Tech., Inc. v. Corozonix Corp., 958 F.2d 1053, 1060 (Fed. Cir. 1992) ("That the product is numerical is not a criterion of whether the claim is directed to statutory subject matter."). *Cf. In re Bilski*, 545 F.3d at 960 n.19 ("As a result, those portions of our opinions in *State Street* and *AT&T* relying solely on a 'useful, concrete and tangible result' should no longer be relied upon.").

237. *AT&T*, 172 F.3d at 1359.

238. *Id.* (citing *Arrhythmia*, 958 F.2d at 1060). *Cf. In re Bilski*, 545 F.3d at 960 n.19 ("As a result, those portions of our opinions in *State Street* and *AT&T* relying solely on a 'useful, concrete and tangible result' should no longer be relied upon.").

239. *See supra* Part I.

240. *In re* Schrader, 22 F.3d 290 (Fed. Cir. 1994).

conducting auctions comprising a series of steps for "competitively bidding on a plurality of related items, such as contiguous tracks of land."[241] The court found that the claimed method was a procedure to determine the best combination of bids.[242] In considering the statutory nature of the claim, Schrader argued that no algorithm was being claimed.[243] The court disagreed, finding that the procedures described the solution of a mathematical problem.[244]

Schrader further argued that despite the presence of the algorithm, the method transformed bidding data into data that could be displayed by regrouping raw bids into new groups known as completions.[245] The Federal Circuit, however, found that there were no physical changes or effects as a result of these regroupings.[246] The patent claim was rejected because the bids were not transformed into a new result, or into a form for display to the bidders.[247]

The previously discussed case of *In re Warmerdam*[248] similarly examined whether the claimed manipulation of data produced a sufficiently transformative effect to render the claim patentable.[249] The court acknowledged that where a claimed process transformed an article and was more than a simple manipulation of ideas, it could be considered statutory.[250] However, the court found that the claimed process did not have the effect of transforming the data into something different.[251]

The informational content of "isolated and purified" genetic sequences is the result of a process which does not transform the information into a different state or thing. Like the information regarding bids in *Schrader*, the information resulting from the process of identification, isolation, purification, or replication is not transformed: it is identical to the information contained within DNA sequences existing within the natural environment. The manipulation of the calculations and the data in the *Warmerdam* case did not produce something different.[252] The isolation, purification and

241. *Id.* at 291.
242. *Id.* at 293.
243. *Id.*
244. *Id.* (citing Gottschalk v. Benson, 409 U.S. 63, 65 (1972)).
245. *Id.*
246. *Id.* at 294.
247. *Id.*
248. *In re* Warmerdam, 33 F.3d 1354 (Fed. Cir. 1994).
249. *Id.* at 1360.
250. *Id.*
251. *Id.*
252. *Id.*

replication of naturally-occurring DNA similarly results in the production of identical genetic information. The requisite transformation for the claimed sequence to be considered statutory subject matter has not been produced by these processes.

A recent decision from the Federal Circuit, *In re Bilski*,[253] clarified the scope of patentable process claims.[254] The case considered whether a business method, where an energy commodity provider manages (hedges) the price risks and consumption risks in the energy market without using a computer, is patentable subject matter.[255] The Federal Circuit ordered this appeal of the lower court decision be heard en banc, and that briefs address specific questions, including whether a method or process must result in the physical transformation of an article or be tied to a machine in order to constitute patentable subject matter. [256]

The court assessed the validity and usefulness of previous and alternative tests for determining whether a patented process totally pre-empts the use of a law of nature, natural phenomenon, or abstract ideas (referred to by the court as "fundamental principles"),[257] and found such tests to be inadequate or improper inquiries for determining whether a claimed process is statutory.[258] Among these was the "useful, concrete and tangible result" language, previously articulated in *Alapatt*, *State Street*, and *AT&T*.[259] The court recognized that "the Supreme Court has explained that 'certain types of mathematical subject matter, standing alone, represent nothing more than abstract ideas until reduced to some type of practical

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

254. *Id.*

255. *See id.* at 949-50.

256. *Id.* at 949-50.

257. *Id.* at 952-61 & n.5.

258. What was known as the "Freeman-Walter-Abele" test consisted of two parts: whether the claimed process contained an "algorithm," as described by the Supreme Court in *Benson*, and then determining whether it was applied or tied in any way to "physical elements or process steps." Because the test both conflicted with the Court's holding in *Flook*, and because claims had been upheld which failed the test, the court held that the test was inadequate, and rather, "the machine-or-transformation test is the applicable test for patent eligible subject matter." *Id.* at 958-59. The court similarly dismissed what was known as the "technological arts test," finding that because the language and meanings of its terms were "ambiguous and ever-changing," and because the test had not been expressly articulated by the Court, or the lower Federal Circuit, they would rely upon the "machine or transformation test as articulated by the Supreme Court." *Id.* at 960. Categorical exclusions, such as "business methods," were beyond the fundamental principles delineated by the Court and were also rejected as exclusions for patentability. *Id.* The "physical steps" test was also rejected, the Court stating that "the proper inquiry under § 101 is not whether the process claim recites sufficient 'physical steps,' but rather whether the claim meets the machine-or-transformation test." *Id.* at 961.

259. *Id.* at 959.

application.'"[260] However, although the court found that this might be helpful in deciding whether a claim was for a fundamental principle or its application, the inquiry was insufficient and should not supplant the Court's test for patent eligibility under § 101.[261]

The court relied on *Benson* and *Flook* to describe essential elements of the test: "the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent eligibility"[262] and "the involvement of the machine or transformation in the claimed process must not merely be insignificant, extra-solution activity."[263] As the case did not deal with the implementation of a machine, the court discussed only the transformation element of the test, clarifying the meaning of "[a] claimed process is patent eligible if it transforms an article into a different state or thing."[264]

The court noted that the facts of the case necessitated a clarification of what constituted an "article" to be transformed.[265] While processes for a chemical or physical transformation of substances or physical objects were "self-evident," the "raw materials" of a claimed process in the "information age" are electrical signals or electronically manipulated data, or in this case, "even more abstract constructs such as legal obligations, organizational relationships, and business risks."[266] The court examined the decision in *Abele*[267] to illustrate how a determination could be made as to whether these types of claimed processes qualify as transforming or reducing an article into a different state of thing.[268]

In *Abele*, one claim was directed to a non-statutory process of "graphically displaying variances of data from average values," where the type and nature of the data was not specified, and the claim did not describe where the data came from or what it represented.[269] However, a claim which specified that the data was "X-ray attenuation data" which had been produced in a two-dimensional field "by a computed tomography scanner" was patentable subject

260. *Id.* (quoting *In re* Alappat, 33 F.3d 1526, 1543 (Fed. Cir. 1994) (elaborating on Supreme Court precedent)).

261. *Id.* at 959.

262. *Id.* at 961 (citing Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972)).

263. *Id.* at 962 (citing Parker v. Flook, 437 U.S. 584, 590 (1978)).

264. *Id.* at 962.

265. *Id.*

266. *Id.*

267. *In re* Abele, 684 F.2d 902 (C.C.P.A. 1982).

268. *Bilski*, 545 F.3d at 962-63.

269. *Id.* at 962.

matter.[270] The visual depiction on a display of data representing physical and tangible objects, bodily organs, bones and tissues, represented a transformation rendering the process patentable.[271] The court reiterated that transforming the electrical data into the visual depiction was sufficient, and that transformation of the physical object represented by the data was unnecessary for upholding the claim.[272] As a result, the basis of the test, as defined by the court, was "the prevention of pre-emption of fundamental principles" was satisfied: the process involved a practical application of a fundamental principle which transformed specific data and a depiction representing physical objects.[273] Accordingly, the claim's scope did not wholly pre-empt the use of the principle.

In examining the claimed risk-hedging method in *Bilski*, the court noted that abstractions such as legal obligations, relationships, or business risks could not be "transformed" as they were neither substances or physical objects or representative of physical substances or objects.[274] As the process was not tied to the use of a machine and was not transformative, the claim was directed to an abstract idea, its use a pre-emption of all forms of the idea, and thus non-statutory subject matter.[275]

In a statement that could prove significant for a consideration of the statutory nature of DNA sequences, the court in *Bilski* noted that future developments in science could cause the Supreme Court to alter or abandon the transformation test in order to "accommodate emerging technologies."[276] It is foreseeable that the evolving nature of the "article" being transformed, such as electronic data or abstract business methods, will be highly relevant in future cases considering the pre-emption of fundamental principles by a patent claim. In such a case involving claims to human DNA sequences, the "article" can be erroneously and archaically described as simply the isolated and purified molecule, a physical object or substance, and the claimed sequence, the specific patterns of As, Ts, Cs, and Gs, simply a representation of that physical molecule. If this reasoning is followed, one could consider the claim analogous to the statutory claim of

270. *Id.* at 962-63.
271. *Id.*
272. *Id.* at 963.
273. *Id.* (articulating the court's understanding of Supreme Court precedent).
274. *Id.*
275. *Id.* at 964-66.
276. *Id.* at 956.

Abele, the specific representative data transformed into a visual depiction on a particular screen.

However, in what the court described as "the information age,"[277] it is important to recognize and regard patent claims for human DNA sequences as *information*. In doing so, these claims fail the machine-or-transformation test. Although the process of isolation and purification might reduce the molecule itself, the actual claim is for the sequence which represents the intangible or embodied information–the formula for the production of proteins. DNA sequences are more analogous to the abstract relationships of *Bilski*, an exchange of potential legal rights to purchase commodities, than electronic data transformed into a visual image. Similarly, the molecule itself can be described as simply embodied or materialized information, the sequence again representative not of a physical object or substance, but of pure and intangible information, a non-statutory abstraction. In either case, patents claiming this information pre-empt the fundamental principle, the pre-existent naturally occurring information of human DNA.

III. CATEGORIES OF STATUTORY SUBJECT MATTER

In defining statutory subject matter, the Court has recognized that a patent is granted for a discovery or invention of a means or method of producing a result, rather than for the result itself.[278] A patent granted to DNA sequences, isolated or otherwise, is a patent granted to information, which is not within the categories defined by statute. Additionally, patents claiming genetic sequences which have been identified, isolated, purified or replicated have been erroneously granted for a "result" and an "effect" of a process that identifies, isolates, purifies, or replicates the information in a human genetic sequence. The sequential information of a human gene is precisely the scientific explanation of the product being claimed. Thus, these sequences are not within the four enumerated statutory categories.

Whereas the previously discussed *Nuijten* case construed the claimed signal as non-statutory pure information, it also considered whether the signal was within the four enumerated statutory categories.[279] In evaluating the claim, a technique to improve the watermarked signal, the Board stated it was not a process, as it did not recite "acts"; it was not a machine, as it lacked a concrete physical

277. *Id.* at 962.

278. Diamond v. Diehr, 450 U.S. 175, 182 n.7 (1981) (quoting Corning v. Burden, 56 U.S. (15 How.) 252, 267-68 (1854)).

279. *In re* Nuijten, 500 F.3d 1346, 1352 (Fed. Cir. 2007).

structure; it was not a composition of matter, as it was "not composed of matter"; and it was not a manufacture, as it did not have any physical structure or fit the definition of a manufacture which requires a tangible object.[280]

In discussing whether the claim constituted any of the statutory categories, the court first reiterated and clarified the *State Street* case.[281] *State Street* suggested that the question of § 101 patentability should focus on the essential characteristics of the claim, particularly its practical utility, rather than the category of subject matter.[282] *Nuijten* found that the four statutory categories should not be rendered irrelevant and non-limiting, noting that *State Street* recognized that the claimed subject matter must qualify as one of four statutory categories.[283] The dispute in this case was whether the transitory signal meets the criteria of *any* statutory category.[284]

The court examined each statutory category in turn. The court found that the claimed invention was not a process as it was not "a series of acts or steps."[285] Nuijten argued that the signal was a process because the signal had to be encoded using a given encoding process. The court viewed this as a potential product by process claim, directed to the ultimate product and not the underlying process.[286] The court stated that the recited steps did not transform a claim for a thing–the signal itself–into a claim for the process by which it was made.[287] Despite the signal's physicality, the court held that the signal was not a machine "consisting of parts, or of certain devices and combination of devices."[288]

The court also found that the signals, standing alone, were not statutory manufactures.[289] The court defined articles of manufacture as either verbs or nouns: as a verb, "the production of *articles* for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand labor

280. *Id.*

281. *Id.* at 1353.

282. *Id.* at 1353-54 (citing State St. Bank & Trust v. Signature Fin. Group, 149 F.3d 1368, 1375 (Fed. Cir. 1998)).

283. *Id.* at 1354.

284. *Id.*

285. *Id.* at 1355.

286. *Id.* (citing SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1315 (Fed. Cir. 2006)).

287. *Id.*

288. *Id.* at 1355-56 (quoting Burr v. Duryee, 68 U.S. (1. Wall.) 531, 570 (1863)).

289. *Id.* at 1356-57.

or by machinery,"[290] or, as a noun, articles resulting from the process of manufacture.[291] The court held that these definitions require articles, or commodities of manufacture, be tangible.[292] Although the transmitted signal was man-made and physical, the court regarded its nature as transient and devoid of any semblance of permanence.[293] Because the signal was not a tangible article or commodity, it was not a manufacture as defined by the statute.

The court also concluded that the signal was not a composition of matter, which the court defined as "all compositions of two or more substances and all composite articles, whether they be the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, [or] powders of solids."[294] Thus, after examining all four categories, the court determined that the signal did not fall within any category of patentable subject matter.[295]

In all of the previously discussed claims to isolated DNA sequences, pure information is the essence of these claims.[296] Analogous to the signal in *Nuijten*, they arguably do not fit into any of the four enumerated categories of statutory subject matter. It is not a process because it is not a series of acts or steps. Simply calling the resultant polynucleotide sequence "isolated" "does not transform a claim covering a thing–the [information] itself–into" a claim that covers the process for making it.[297] Nor is isolated DNA a machine because it is not a concrete thing consisting of parts or of certain devices or combination of devices. A claim for a polynucleotide construed to cover its informational content similarly is not a manufacture or article resulting from the process of manufacture. The information comprising an isolated DNA sequence does not have a new form, use, quality, properties, or combinations of information differing from the raw material from which it has been extracted. Analogous to a signal, genetic sequence information is intangible and thus does not constitute a manufacture according to the statute and the court.

Furthermore, a claimed polynucleotide sequence is not a composition of matter. Whether existing in its natural environment or

290. *Id.* at 1356 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980)).

291. *Id.* (citing Bayer AG v. Housey Pharms., Inc., 340 F.3d 1367, 1371-72 (Fed. Cir. 2003)).

292. *Id.*

293. *Id.*

294. *Id.* at 1357 (quoting *Chakrabarty*, 447 U. S. at 308).

295. *Id.*

296. *See supra* Part I.

297. *See Nuijten*, 500 F.3d at 1355.

extracted from that environment, the claimed DNA sequence is not a composition of two or more substances. Rather, it is simply intangible or embodied information–the representation or embodiment of a pre-existent *arrangement*, as opposed to a newly composed mixture, union, or combination of chemicals–the sequence coding for the same amino acids whether inside or outside an individual's body. The polynucleotide, like the signal, is not a statutory composition of matter, nor is it a statutory process, manufacture, or machine.

A. Non-statutory "printed matter"

Under the "printed matter" doctrine, a mere arrangement of printed matter by itself is not considered a manufacture and is not patent eligible subject matter.[298] In the computer age, electronic storage and communication of information is widely used. Accordingly, "the printed matter rule extend[s] beyond printed information to information recorded in any medium or substrate."[299] It is arguable that as "printed matter," patent claims directed to DNA sequences read on a simple arrangement of numerical information recorded in an identified molecule and are outside the scope of statutory subject matter.

Older cases illustrate the doctrine. In the 1931 case of *In re Robert Russell*,[300] a patent was sought for a novel way of arranging and grouping names, which facilitated their location in directories and indexes. [301] Although tangible and novel, the court found the arrangement to be printed matter outside the statutory categories.[302] Similarly, the 1926 case of *Guthrie v. Curlett*[303] involved an index that consolidated all railroad tariffs in the country using symbols representing carriers, terminals, and commodities.[304] Although the court found a compression of information using indices useful,[305] this was not enough to confer patentability as no new relationship existed between the printed matter and physical matter.[306]

298. *See In re* Miller, 418 F.2d 1392, 1396 (C.C.P.A. 1969); *Ex parte* Gwinn, 112 U.S.P.Q. 439, 442 (Pat. Off. Bd. App. 1955); *In re* Jones, 373 F.2d 1007, 1013 (C.C.P.A. 1967) (quoting *In re* Sterling, 70 F.2d 910, 912 (C.C.P.A. 1934)).

299. CHISUM, *supra* note 47, § 1.02[4] (citing *In re* Lowry, 32 F. 3d 1579 (Fed. Cir. 1994); *In re* Jones, 373 F.2d 1007 (C.C.P.A. 1967); *Ex Parte* Jenny, 130 U.S.P.Q. 318 (Pat. Off. Bd. App. 1960)).

300. *In re* Russell, 48 F.2d 668 (C.C.P.A. 1931).

301. *Id.* at 668.

302. *Id.* at 668-69.

303. Guthrie v. Curlett, 10 F.2d 725 (2d Cir. 1926)

304. *Id.* at 726.

305. *Id.*

306. *Id.* at 726-27.

In *Boggs v. Robertson*,[307] a new method for making map projections was claimed which used geometrical curves for a particular purpose.[308] The court found that the claimed invention was merely a system of lines which did not refer to any tangible article.[309] Because there was no dependence between the printed matter and the object on which it was arranged, the court held the invention to be an idea reduced to writing.[310] The surface upon which the projection was reproduced, or how the projection was affected, was immaterial and completely lacking in substance.[311] The court described the claims as merely "mental visions" and held that the claim was not a manufacture.[312]

Claims to the sequential informational content, to the representations of the physical arrangements of chemical bases of human DNA sequences, are analogous to the non-statutory claims involved in the printed matter cases. One can consider the polyribose-phoshodiester backbone of DNA, i.e., the materials which shape the physical double helix form of a DNA molecule, as a substrate similar to a blank sheet of paper. The unique nucleotide bases which specify the genetic code are the letters or indicia of information. The backbone itself is generic; it does not specify any genetic information and can accommodate any letters without preference. The blank substrate is of no particular value as the essence of the subject matter of a DNA sequence claim.

This recitation of the sequence information in a patent claim is analogous to a way of arranging and grouping names in an index–the non-statutory claim in *Russell*. It is "a mere arrangement of printed matter," where the substrate is not a sheet of paper or a book, but the molecule from which the information is derived.[313] Thus, the claimed invention should not qualify as one of the four enumerated categories of statutory subject matter.

As in *Guthrie*, the "employment of symbols" used to make an index consolidating tariffs, the subject matter being claimed for patents on human genetic sequences are symbols for an arrangement of chemical bases occurring naturally. The metaphor of letters in the

307. Boggs v. Robertson, 13 U.S.P.Q. 214 (D.C. 1931).
308. *Id.* at 214.
309. *Id.* at 215.
310. *Id.*
311. *Id.*
312. *Id.*
313. *In re* Russell, 48 F.2d 668, 669 (C.C.P.A. 1931).

alphabet has been used to describe this information,[314] and today these representations should also be unsuitable, non-statutory subject matter. Despite the nomenclature, "isolated and purified" is not what is described by the claiming party. In the case of *Boggs*, the use of geometric curves was considered an abstraction resembling a mental vision. The erroneously described manufacture lacked material substance.[315] Like all cases in the printed matter doctrine, the sole feature of the alleged novelty is an abstraction, independent of its material substrate.[316] Patent claims to identified, isolated, purified, and replicated genetic information are also allegedly novel, but could be described as mere abstract ideas reduced to writing or mental visions. The substrate, the backbone of the molecule, is similarly irrelevant to the basis of the claim.

As an exception to this traditional rule, claims to printed matter became patentable if an arrangement involved "a new and useful feature of physical structure or a new relationship between the printed matter and the physical structure."[317] Cases have been distinguished where the claimed invention was a physical object which had been designed in a manner specific to its unique construction and where the printed matter provided a physical relationship, a "cooperation between the body and the indicia."[318]

This exception is illustrated in older cases such as *Benjamin Menu Card v. Rand McNally & Co.*[319] and *Cincinnati Traction Co. v. Pope*.[320] In the 1894 *Benjamin* case, a patent was sought for a menu used in railway cards with two detachable checks on its reverse side.[321] When a check was detached, the menu was mutilated, the remainder of which was incomplete and useless for another guest.[322] The court held that the combined menu-meal ticket was patentable, finding that a structure made of cardboard with printed matter upon it did not render the invention non-statutory.[323]

The 1913 *Cincinnati* case questioned whether a "time limit" transfer ticket used by street railways and transfer companies that enabled quick transfer and the monitoring of conductors and

314. *See, e.g.*, Kane, *supra* note 134, at 754.
315. *Boggs*, 13 U.S.P.Q. at 215.
316. *See id.* at 214.
317. CHISUM, *supra* note 47, § 1.02[4].
318. *Boggs*, 13 U.S.P.Q. at 215.
319. Benjamin Menu Card v. Rand, McNally & Co., 210 F. 285 (N.D. Ill. 1894).
320. Cincinnati Traction Co. v. Pope, 210 F. 443 (6th Cir. 1913).
321. *Benjamin Menu Card*, 210 F. 285-86.
322. *Id.* at 286.
323. *Id.* at 288.

passengers was patentable subject matter.[324] The ticket contained the usual notation but included detachable coupons for morning and afternoon uses, whereas the earlier method of punching a ticket allowed for its fraudulent use.[325] The court held that the new ticket clearly involved a physical structure and that the claim was limited to that structure.[326] Thus, it was deemed a patentable manufacture.[327] The court found the distinctive structure of both the body and the coupon to be accompanied by instructions for use and interpretation of the ticket.[328] The construction of the transfer ticket did not confine the specifications of the style, printed arrangement, or its language.[329] The only necessity was that the face of the ticket conveyed the required information.[330]

A more recent 1994 case dealing with computer technology, *In re Lowry*,[331] also discussed the printed matter doctrine.[332] The Federal Circuit explained that a computer's memory stores data according to a particular order or arrangement and that application programs use this stored data to perform specified functions.[333] A framework for organizing and representing this information is called a "data model," which in turn defines data structures, where an application program uses organizational structures imposed upon the data, compatible with particular data processing systems.[334] Thus, these structures are a physical embodiment of a data-organizing system, often shared by more than one program.[335] The patent claim at issue was directed to a data structure that allowed accessibility by different application programs by optimizing the capacities of two different data models that were both functionally and structurally

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324. *Cincinnati Traction*, 210 F. at 444.

325. *Id.* at 446, 448 ("Claim 1 reads: 1. A transfer ticket comprising a body portion and a coupon, said body portion and coupon bearing conventional indications to constitute an antemeridian transfer ticket when said body portion is used separately and a postmeridian transfer ticket when used together. . . Claim 8 reads: 8. A transfer ticket comprising a body portion and a coupon and further provided with conventional indications to constitute a complete transfer ticket for one part of the day when said body portion and coupon are used together.").

326. *Id.*

327. *Id.*

328. *Id.*

329. *Id.* at 446-47.

330. *Id.* at 447.

331. *In re* Lowry, 32 F.3d 1579 (Fed. Cir. 1994).

332. *Id.*

333. *Id.* at 1580.

334. *Id.*

335. *Id.*

expressive.[336] Thus, the structure allowed for both large and varied amounts of data to accurately represent complex information.[337]

Lowry's data structure was comprised of ADOs (Attribute Data Objects) stored in a memory. ADO's were defined as basic data elements comprised of sequences of bits stored in the memory as electric or magnetic signals representing information.[338] According to the claim, these ADOs have interrelationships arranged in both a hierarchal and non-hierarchical manner and are governed by simple organizational rules.[339] "Because the claimed invention use[d] single ADOs governed by simple organizational rules, Lowry assert[ed] that it may flexibly and accurately represent complex objects and relationships."[340] He claimed that the arrangement facilitated software operations in the data structure, including the retrieval, addition, and removal of information.[341] Claims 1-5 claimed "a memory containing a stored data structure."[342]

The court reviewed the Board's determination that the data structures were analogous to printed matter, and therefore, the ADOs' specific features were not patentable without a functional relationship between the printed matter and the substrate.[343] The court found, however, that the cases dealing with printed matter have no relevance where the claimed invention requires that the information be processed by a machine, i.e., a computer, and not the human mind.[344] Because Lowry's data structures are processed by a machine, the court concluded that the printed matter cases were irrelevant to the case at bar.[345]

Additionally, the court noted that the data structures were not analogous to printed matter as the ADOs were not simply underlying data in a database.[346] Instead, the court found that the claims were not merely for the informational content of the computer's memory, but

336. *Id.*

337. *Id.* (Lowry's structure was based upon a model, "Attributive data model," representing complex information in terms of the relationships between attributes, i.e., "the idea that one thing is attributed to another thing." The model capitalized on the concept of a database where information was "represented in terms of its characteristics and relationships to other information," known as attributions.).

338. *Id.* at 1580-81.

339. *Id.* at 1581.

340. *Id.*

341. *Id.*

342. *Id.*

343. *Id.* at 1582.

344. *Id.* at 1583 (quoting *In re* Bernhart, 417 F.2d 1395, 1399 (C.C.P.A. 1969)).

345. *Id.*

346. *Id.*

rather the structures defined the memory's functional characteristics.[347] The court explained that the claims required specific electronic structural elements to "impart a physical organization on the information stored in memory."[348] Lowry did not seek to patent an abstract data model or the informational content residing in a database. Rather, the claimed data structures "impose[d] a physical organization on the data."[349] Considering the issue of a lack of a per se physical structure, the court concluded that if a machine is programmed in a new and unobvious way, it is physically different from a machine without the program because the arrangement of its memory elements is altered.[350]

These exceptions to the printed matter doctrine should not be applicable to patents claiming the sequential information of DNA. In the case of claims to human genetic material, the process of isolation and purification is used to identify and reveal the indicia. Consisting of the information, the sequence is analogous to an arrangement of symbols representative of the physical object. When this arrangement of "identifiers" is patented, there is no new physical body supplemented by indicia which is being claimed. Rather, it is the indicia itself for which the patent is being sought, and is thus indistinguishable from non-statutory printed matter claims. Unlike the menus in *Benjamin* or the time-limit transfer railway tickets in *Cincinnati*, patent claims for the information in a DNA sequence do not "clearly involve physical structure," nor are the claims "limited to such structure."[351] There is no new object that is "accompanied by the conventional indications."[352] The information of a DNA sequence *is the conventional indication*, standing alone.

Unlike the data structures and ADOs of *Lowry*, information existing within claimed DNA sequence is analogous to the information stored in a database. Lowry's claims were directed to more than just the informational content. While the information content affected the exact sequence of bits stored in the data structure, the claims required specific *electronic structural elements* which imparted a physical organization on the information stored in memory. Lowry did not claim the data model in the abstract or the content of information resident in the database. Even though these

347. *Id.*
348. *Id.*
349. *Id.*
350. *Id.* (quoting *In re* Bernhart, 417 F.2d 1395, 1400 (C.C.P.A. 1969)).
351. Cincinnati Traction Co. v. Pope, 210 F. 443, 446 (6th Cir. 1913).
352. *Id.*

structures were imperceptible, they were more than mere abstractions or printed matter. Instead they determined how information was to be managed. In claims for the information in DNA sequences, identifying, isolating, purifying the information in a DNA molecule does not impose a new structure which *imparts* a physical organization of the information. Rather, it merely reflects or represents the identical physical organization. Claims to human genetic sequences are analogous to the distinctions articulated in *Lowry* that were attempts to claim the abstract data model and the informational content of the database. Unlike the data structures in *Lowry*, the information of DNA is analogous to printed matter, and thus non-statutory.

B. Non-Statutory "Mental Steps" or "Mental Processes"

Various explanations have been offered for the mental steps doctrine, including the concern that patents should not be issued for processes involving human thought, communication, understanding, and creativity.[353] A line of cases exemplify the doctrine, including recent cases from the Federal Circuit, which have seemingly revived the doctrine's use.[354]

As noted in *Benson*, mental processes are underlying requisites for work in science and technology.[355] Systems that operate and depend solely on human intelligence to solve practical problems are thus unpatentable.[356] Information-processing methods and analytic processes which are no more than a series of mental steps, or information-processing steps that could be implemented through the use of these mental steps, have been deemed non-statutory by the Patent Office as well as the lower courts.[357] These claims recite purely mental terms such as "determining," "registering," "counting," "observing," "measuring," "comparing," "recording," and "computing."[358]

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353. Richard S. Gruner, *Intangible Inventions: Patentable Subject Matter for an Information Age*, 35 LOY. L.A. L. REV. 355, 400-01 (2002).

354. *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 67 (1972); *In re* Abrams, 188 F.2d 165, 169 (C.C.P.A. 1951); *Ex parte* Read, 123 U.S.P.Q. 446 (Pat. Off. Bd. App. 1943); *In re* Meyer, 688 F.2d 789, 794-95 (C.C.P.A. 1982); *In re* Sarkar, 588 F.2d 1330, 1333 (C.C.P.A. 1978); *In re* Musgrave, 431 F.2d 882, 889 (C.C.P.A. 1970; *In re* Comiskey, 554 F.3d 967, 979-80 (Fed. Cir. 2009); *In re* Bilski, 545 F.3d 943, 952 (Fed. Cir. 2008), *petition for cert. filed*, 77 U.S.L.W. 3442 (U.S. Jan 28, 2009) (No. 08-964).

355. *Benson*, 409 U.S. at 67 (quoting Mackay Radio & Tel. Co. v. Radio Corp., 306 U.S. 86, 94 (1939)).

356. *In re Comiskey*, 554 F.3d at 980.

357. *See, e.g.*, *In re Abrams*, 188 F.2d at 170.

358. *Id*. at 169.

Claims for methods and materials (the informational content of any particular DNA sequence) consisting of a process for determining the presence or absence of susceptibility to a particular disease or condition,[359] should be considered exceptions to patentable subject matter as laws of nature and pre-existing scientific principles.[360] In addition, the subject matter of such claims should be considered mental steps or processes, exclusions to the enumerated statutory categories. These claims are precisely mental activities involving human "communication, creativity, and understanding."[361]

At issue in *Ex parte Read* was the patentability of a method for determining the speed or distance traveled by an aircraft.[362] Claim 8 recited:

> 8. The method for determining the rate of travel of a vehicle which comprises providing two logarithmic scales, starting one of said scales moving relatively to the other, at a rate which changes in accordance with the same logarithmic scale, as the vehicle passes one point of two, the distance between which is known, and as the vehicle passes the other point reading the time rate on one of said scales opposite the distance traveled between said points on the other of said scales.[363]

The court found that this correlation between the readings was not a true manipulative step, but rather a purely mental act.[364] The claim was rejected as it did not constitute a true method.[365]

In the case of *In re Meyer*,[366] the court considered whether a claimed "process . . . for carrying out the process of testing a complex system and analyzing the results of these tests" was statutory subject matter.[367] The human body was described as the "complex system," and the "tests" were part of a clinical neurological examination administered by a physician.[368] The claim noted that in a large number of test outcomes, the use of an algorithm to locate probable functioning and malfunctioning in that system could avoid the

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359. *See supra* note 102 (describing this particular type of claim).
360. *See supra* notes 104-277 and accompanying text.
361. *See supra* note 353 and accompanying text.
362. *Ex parte* Read, 123 U.S.P.Q. 446, 447 (Pat. Off. Bd. App. 1943).
363. *Id*. at 446.
364. *Id*. at 447.
365. *Id*.
366. *In re* Meyer, 688 F.2d 789 (C.C.P.A. 1982).
367. *Id.* at 790.
368. *Id.* at 790-91.

complex task of such a computation.[369] Claim 1 was for steps (a)-(f) which:

> (a) select[ed] a plurality of elements in the complex system . . . ;
>
> (b) initializ[ed] a factor associates with each of [those] elements;
>
> (c) tested the complex system for a response, which response, if effective, require[d] proper functioning of certain said elements, the probable identity [*sic*] of at least some of these certain elements being known;
>
> (d) determin[ed] whether said response of the complex system was at least partially effective or ineffective;
>
> (e) modif[ied] the factor associated with at least some of said elements known to be possible [sic] involved in the response in accordance with the effectiveness of the response; and
>
> (f) repeating steps (c), (d), and (e) for further responses of the complex system to obtain resultant factors for at least some of said elements,
>
> whereby said resultant factors are indicative of probable malfunction of their associated elements and thereby indicative of probable malfunction at the locations of these elements. [370]

In assessing the claim, the court noted that the testing was simply a gathering of data, which was insufficient to render the claim statutory.[371] Step (d) provided information read into a computer, and the comparison process of step (e) took place in the computer by a process in which test outcomes were compared with stored data.[372] The addition of factors and repetition of the computing was not a process for producing a product, such as the process in *Diehr*. Rather it was an attempt to patent a mathematical algorithm.[373]

The court noted that "some mathematical algorithms and formulae do not represent scientific principles or laws of nature; they represent ideas or mental processes and are simply logical vehicles for communicating possible solutions to complex problems."[374] The invention, in part, employed a computer to replace the thought processes of a neurologist. The court addressed "whether [the] mental

369. *Id.* at 791.

370. *Id.* at 792-93.

371. *Id.* at 794 (citing *In re* Richmond, 563 F.2d 1026, 1030 (C.C.P.A. 1977)).

372. *Id.*

373. *Id.*

374. *Id.* at 794-95.

process is applied to [statutory] physical elements or process steps."[375] Construing the claim broadly, the court held that the appellants claimed a mathematical algorithm. It simply represented a mental process that had not been applied to statutory physical elements or process steps and is not within the categories of patentable subject matter.[376]

In the case of *In re Sarkar*,[377] the court examined whether a method of "mathematically modeling an open channel" was a statutory process.[378] The claimed system could "accurately provid[e] the flow parameters . . . over a period time, even though it (1) contains obstructions . . . , (2) experience[d] flooding, (3) ha[d] a lateral inflow, (4) ha[d] actual inflow at its upstream end, and (5) emptied into a tidal body."[379] The ability to account for these situations was asserted to be the advancement, the improvement over the prior art, claimed by the invention.[380] Claim 1 involved a series of steps using repeated mathematical equations:

> [Step] (a) measur[ed] the cross-sectional dimensions of the channel at a specificially chosen, predetermined number of locations usable for schematizing said dimensions into a rectangularized cross-section for each regularly spaced but arbitrarily chosen distance Δx along the length of the channel irrespective of the chosen value of the interval of time Δt;
>
> . . . .
>
> Step (b) recite[d] the mathematical equations used to define the open channel flow. Steps (c)-(g) recite[d] additional data-gathering steps, and step (h) recite[d] the method of solving the flow equations using the collected data of steps (a) and (c)-(g).[381]

The Board rejected all of the claims, concluding that they were not directed to a statutory process.[382] Step (a) was considered an older, common step to establish values for variables in equations and, if patented, would pre-empt all meaningful uses of the recited formulas.[383]

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375. *Id.* at 795-96.
376. *Id.* at 796.
377. *In re* Sarkar, 588 F.2d 1330 (C.C.P.A. 1978).
378. *Id.*
379. *Id.* at 1331.
380. *Id.*
381. *Id.*
382. *Id.*
383. *Id.* at 1332 (citing *In re* Christensen, 478 F.2d 1392, 1394 (C.C.P.A. 1973)).

Considering whether the measuring step (a) established that the invention as a whole was an application of the algorithm, not simply the algorithm itself, the court noted that a number of claims have been considered to be unpatentable mental steps, as they involve disembodied thoughts rather than tangible embodiments of ideas in the technological arts.[384] Continuing, the court stated that the human mind is capable of mental processes such as mathematical exercises or calculations. Although often represented as algorithms, formulas, symbols, or equations, these mathematical thought processes remain disembodied and are therefore not within the categories of patentable subject matter.[385]

The court disagreed with Sarkar's proposition that his invention was an inventive application of the algorithm.[386] Instead, the court explained that a mathematical equation cannot be used without "establishing and substituting values" for its variables.[387] This substitution of values has been viewed as a type of mathematical step. If the sole steps of gathering and substituting values were sufficient, every algorithm, mathematical equation, or formula with a practical use would be a patentable process. The substitution of specific values used to convert the ideas in the formula into an application of the formula is non-statutory.[388] The court concluded that as a whole, Sarkar's claimed invention is a mathematical exercise where a new formula is provided; values that have been dictated by the formula are gathered and substituted for the formula's variables, and the formula's calculations are made.[389] The claim was rejected by the court as a non-statutory process.[390]

The previously discussed patent on a method of identifying an individual at risk for having a genetic predisposition to developing breast cancer is analogous to cases determining particular processes or methods to be non-statutory "mental processes" or "mental steps."[391] Akin to reading the scales in *Ex parte Read*, the patent requires reading the information produced by similar data gathering and calculations, and determining susceptibility to breast or ovarian cancer based upon the presence or absence of a genetic variation.

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384. *Id.* at 1333 (citing *In re* Waldbaum, 457 F.2d 997, 1003 (C.C.P.A. 1972)).

385. *Id.*

386. *See id.* at 1335-56.

387. *Id.* at 1335

388. *See id.* (citing *In re* Chatfield, 545 F.2d 152, 158 (C.C.P.A. 1976)).

389. *Id.* at 1336.

390. *Id.*

391. *See supra* notes 89-92 and accompanying text (discussing a specific example of this type of claim).

Like the neurological tests in *Meyer*, the identification of a persons' DNA sequence by amplifying the fragment (using an oligonucleotide primer which hybridizes to a sequence within the gene) and repeating these sequencing processes are simply steps to gather data.[392] The machine's comparison process in *Meyer* recognized the "malfunction probabilities for all elements of a complex system," in other words, neurological problems within an individual's human body. This is analogous to a geneticist or physician determining that the presence or absence of a particular polymorphic variation represents the "malfunction probabilities" of a particular genetic variation which might similarly produce problems within a person's body.

The correlation involved in the patent for breast cancer susceptibility, like the computer process of *Meyer*, is analogous to a mathematical algorithm, a scientific formula, rather than a process which produces a product as in *Diehr*.[393] Instead of *replacing* the "thinking processes of a neurologist with a computer,"[394] the claimed genetic information patent *excludes* the thought processes of any physician, researcher, geneticist, scientist or individual who wishes to make a similar determination by examining data and recognizing that such a correlation exists. Like the claimed algorithm in *Meyer*, these claims are directed to a non-statutory mental process which is not tied or applied to either physical elements or process steps, and is thus not within any of the four enumerated statutory categories.[395]

As in *Sarkar*, the gathering of information involved in sequencing an individual's DNA to establish the existence of a susceptibility to a particular genetic condition is analogous to the similarly described steps of establishing values for an equation's variables used to effectively model an open channel.[396] Determining that a correlation exists by comparing the information gathered via DNA sequencing is similarly a disembodied exercise within the range of human mental processes.

A line of cases has clarified the mental steps doctrine.[397] In a rehearing of a previous decision, *In re Prater*,[398] the court examined

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392. *In re* Meyer, 688 F.2d 789, 794 (C.C.P.A. 1982) (explaining that the testing step is merely a step to gather data).

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

394. *Id.* at 795.

395. *Id.* at 796.

396. *In re* Sarkar, 588 F.2d 1330, 1333 (C.C.P.A. 1978).

397. *See, e.g.*, *In re* Abrams, 188 F.2d 165 (C.C.P.A. 1951); *In re Meyer*, 688 F.2d; *In re Sarkar*, 588 F.2d; *In re* Musgrave, 431 F.2d 882 (C.C.P.A. 1970).

the mental steps doctrine in the context of considering whether a particular method claim constituted patentable subject matter.[399] "The invention include[d] both a method and apparatus for the processing, or analysis, of conventionally obtained spectrographic data to produce a quantitative spectrographic analysis of a qualitatively-known mixture, for example a mixture of gases, by which the unknown component concentrations maybe determined with minimum of error."[400]

Prior to the claimed invention, the raw data was obtained in a spectrogram at a "continuous trace having a plurality of peaks."[401] A subset of equations was applied to the data to solve for the concentrations to produce a quantitative analysis.[402] The description of the invention noted:

> (1) that the different subsets of equations result in varying degrees of undesired "error amplification" in transforming the spectrographic data involving peak heights to the desired concentrations; (2) that there exists a certain relationship indicative of such error amplification; (3) that that relationship is related to, and may be expressed in terms of, the determinants of subsets of the equation, the determinant of largest magnitude indicating the subset of equations involving the least error amplification.[403]

Prior to the claimed invention, no systematic method or means existed to select the subset of equations that would generate the least error amplification.[404] Additionally, the applicants disclosed a detailed, mechanical machine to carry out the invention. They noted that this was one device capable of performing the functions and that a general purpose computer could also be used.[405]

The Board rejected claims 1, 6-9, 12, and 17-21 because the method did not set forth anything which could not be performed purely as a mental exercise,[406] and also determined that Claim 10 was an "apparatus counterpart" to the non-patentable method.[407] The appellants sought to assert that the mental steps rule should not apply

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398. *In re* Prater, 415 F.2d 1378 (C.C.P.A. 1968), *rev'd in part on reh'g*, 415 F.2d 1393 (C.C.P.A. 1969).

399. *In re* Prater, 415 F.2d 1393 (C.C.P.A. 1969).

400. *Id. at* 1395.

401. *Id.*

402. *Id.* at 1395-96.

403. *Id.*

404. *Id.*

405. *Id.* at 1396-97.

406. *Id.* at 1395, 1398.

407. *Id.* at 1399.

by noting that in previous cases, no machine or apparatus had been disclosed for automatically carrying out the invention without human intervention. [408] This rationale precluded "the process or any part thereof from being considered purely mental."[409] The court agreed with the appellants, distinguishing their method claim from the one in *Abrams*, where the teachings of an application could only be performed in the mind, and *Yuan*, where the claimed invention was an operator's interpretation of results performed in his mind with the use of equations, pencil and paper.[410]

Further delineating the mental steps doctrine in footnotes, the court explained that purely mental steps "may only be performed in, or with the aid of, the human mind."[411] Physical steps "may only be performed by physical means, machinery, or apparatus."[412] Noting their differences, specifically that mental steps were less susceptible to specific definition, the court described a spectrum whereby an infinite variety of steps could be employed in between either purely mental or purely physical means including "comparing" or "determining."[413] The court stated that to determine which end of the spectrum is nearer, each case, considering all of the surrounding circumstances, must be decided on its own facts.[414] Regarding the particular issue in the case, the court stated "it would appear that the *disclosure* of apparatus for performing the process wholly without human intervention merely shows that the disclosed process does not fall within the so-called 'mental steps' exclusion."[415]

The court, in *In re Musgrave*,[416] discussed the mental steps doctrine when deciding whether a claimed process for obtaining seismograms which delineated the nature of the subsurface formations in the earth's crust was a statutory process.[417] The claimed invention for a "new" seismogram was accomplished by identifying and eliminating "multiples." Caused by reflections of seismic waves, multiples were the "unwanted signals which needed to be eliminated to avoid errors in measurements of the time-occurrence of

408. *Id.* at 1400.

409. *Id.* at 1400.

410. *Id.* (discussing *In re* Abrams, 188 F.2d 165 (C.C.P.A. 1951); *In re* Yuan, 188 F.2d 377 (C.C.P.A. 1951)).

411. *Id.* at 1402 n.22.

412. *Id.*

413. *Id.*

414. *Id.*

415. *Id.*

416. *In re* Musgrave, 431 F.2d 882 (C.C.P.A. 1970).

417. *In re Musgrave*, 431 F.2d at 882, 888.

reflections."[418] The court found the discovery to consist of techniques to identify and eliminate the multiples when they could be separated from reflections and the "magnitude of errors in the normal move-out corrections [could] be determined."[419] Thus, it was possible for multiples to be removed from the seismograms.[420] In order to employ the techniques, the seismograms must be reproduced phonographically on a magnetic, photographic, or other reproducible medium.[421] This technique was necessary as the refinement of the seismograms involved a repetition of recording and playing back the signals which represented the seismic waves.[422]

The Board rejected the claims as they included no physical steps and set forth only a method of processing data that did not require any tangible device.[423] The Board found that corrections applied in steps 2 and 3 of Claim 2 resulted from the human judgment implicit in step 1, where the signals generated at detecting stations were a necessary step that required compilation of data from two sources.[424] The Board also found that step 3, where these corrections had to be further "interpolated," was likewise an act requiring human judgment, and step 6 merely applied corrections to the data and required no physical act.[425]

The Board concluded that the claim and its steps covered non-statutory subject matter.[426] What distinguished these claims from conventional methods of seismic exploration was the use of every possible procedure, including mere mental processing of the data, for applying correction data to experimental data.[427] They similarly rejected Claim 60 as a method for processing data which did not specify or require using an apparatus or employing physical acts on physical things.[428] Accordingly, the Board considered the method, a series of conceptual steps, a non-statutory algorithm.[429]

Differing from the Board's interpretation, the court discussed how the concept of "purely mental" should be interpreted, noting that

418. *Id.* at 884.
419. *Id.*
420. *Id.*
421. *Id.*
422. *Id.*
423. *See id.* at 886.
424. *See id.* at 887.
425. *Id.* at 887-88.
426. *Id.* at 885.
427. *Id.* at 888.
428. *Id.*
429. *Id.* at 886, 888.

the correct construction should "encompass only steps incapable of being performed by a machine or apparatus."[430] In a footnote, the court discussed what "particularly human activities" involved, including the following description:

> None of the steps involve peculiarly human mental activities which cannot, in principle, be performed by devices. None of them involve aesthetic, emotional, imaginative, or creative thought or reactions on the part of the practitioners (operators). None of them involve human "value judgments"–that is, judgments on human conduct, ethics, morals, economics, politics, law, aesthetics, etc.[431]

In considering whether the claims involved purely mental steps, the court examined a number of Board reversals of "mental steps" rejections.[432] In *Ex Parte Moser*,[433] while stating that determining a relationship between viscosity and the Conradson carbon of cattle feed was in essence a mental process, the continual measuring of the feed's viscosity into a machine was not a wholly mental step.[434] In *Ex Parte McNabb*,[435] a multi-step method of locating defects in wooden objects such as telephone poles by radiographic methods, which included physical manipulations based upon observations, did not involve "purely mental or interpretative mental steps."[436] In *Ex parte Kahn*,[437] the Board considered whether a method of insect control, where insects were selectively attracted according to species, was non-statutory subject matter according to the "mental steps" exclusion.[438] The sound of a female insect was recorded while she was feeding around sunrise and sunset.[439] The signal was then modified by amplifying the high-frequency component. The marked portions of the modified signal were rerecorded and reproduced in front of the live insects to be controlled.[440] The Board found that the captive insects indicated the parts of the record attractive to them and selected for those insects; the operator observed this fact and marked

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430. *Id.* at 889-90.

431. *Id.* at 890 n.4 (quoting Robert Coulter, *The Field of the Statutory Useful Arts*, 34 J. PAT. OFF. SOC'Y. 417, 426 (1952)).

432. *Id.* at 891.

433. *Ex Parte* Moser, 124 U.S.P.Q. 454 (Pat. Off. Bd. App. 1959).

434. *Id.* at 455.

435. *Ex Parte* McNabb, 127 U.S.P.Q. 456 (Pat. Off. Bd. App. 1959).

436. *Id.* at 457-58.

437. *Ex Parte* Kahn, 124 U.S.P.Q. 511 (Pat. Off. Bd. App. 1959).

438. *Id.* at 512.

439. *Id.*

440. *Id.*

the record.[441] The Board found that while the operator should think while observing whether the record was attracting the captive insects, the claimed steps did not involve such thought and thus did not describe the claims as mental processes.[442]

In *Musgrave*, the court was not concerned with the Board's conclusions regarding the non-statutory nature of individual steps 2 and 3 of Claim 2. The court was only concerned with whether the *combined* steps which constituted the claimed process were statutory, finding that both claims 2 and 60 basically involve manipulating certain "signals" to achieve an improved record of seismic events.[443] The court reasoned that these claimed processes were not non-statutory mental processes simply because some or all of the steps could also be carried out in the human mind or because the performance of the process required thought.[444] The only requirement to make a series of steps a statutory process is that it be within the technological arts.[445]

Distinguishable from the claims in *Prater* and *Musgrave* are patent claims on methods and materials for identifying individuals having an allele of their BRCA1 gene with a BRCA coding sequence not associated with breast or ovarian cancer, and determining that this data is correlated with an absence of a genetic susceptibility to the disease. A process which, to date, can only be performed in the human mind.[446] Although techniques to gather and compare such biological data are presently automated using sequencing/microarray technology in conjunction with a computer-implemented comparison and a statistical analysis of the collected data, it is arguable that these physical steps, machines, and apparatuses do not recognize and understand the implications of the existing statistical "correlation." This is highly distinguishable from the correlation which has occurred in the mind of the individual reading the statistical data. Moreover, in examining the spectrum to determine whether a step is physical or mental, considering the specific circumstances of the patent claims to these genetic correlations leads to a further distinction that invokes the mental steps exclusion. In *Prater*, a machine or a computer could employ a mathematical formula to refine seismograms and determine "an unknown component concentration" with a "minimum of error"

441. *Id.* at 514.
442. *Id.*
443. *In re Musgrave*, 431 F.2d 882,893 (C.C.P.A. 1970).
444. *Id.*
445. *Id.* (citing U.S. CONST. art. I, § 8, cl. 8).
446. *See supra* note 103 and accompanying text.

where the machine, apparatus, or computer is *producing* the determination.[447] In the case of patents on methods for identifying genetic relationships, it is the thought itself, i.e. a determination which is being patented. The recognition of the disembodied sequence information representing the correlation is *made*, not by a machine, apparatus, or computer, but by the mental step of *anyone* recognizing what the information represents.

The patenting of this genetic information, the assertion that certain bits of sequence information is determinative of, identifies, or correlates to the presence or absence of an increased susceptibility to a certain disease, is also distinguishable from the court's holding and analysis in *Musgrave*. Attempting to define the concept of "purely mental," the court in *Musgrave* noted that it involved "particularly human activities."[448] Any recognition of a genetic correlation (by an "operator" or otherwise) is an activity involving aesthetic, imaginative and creative thought–albeit scientific (it is a *scientific* judgment, an "etc." similarly referred to in the *Musgrave* analysis).[449]

Patents on genetic correlations similarly are distinguishable from the cases cited by *Musgrave* whose claims were not considered "mental steps." In *Ex Parte Moser*, the court was not satisfied that recognizing the viscosity of the feed using a machine was a wholly mental step.[450]

In the claim for a method of identifying individuals with or without a susceptibility to breast or ovarian cancer, it is the recognition of the relationship, i.e., a mental process that is patented. The previously claimed method, involving the sequences of BRCA genes, states that steps in the method are;

> e) determining the presence or absence of each of the polymorphic variations in said individual's BRCA1 coding sequence . . . .
>
> f) determining any sequence differences between said individual's BRCA1 coding sequences and SEQ. ID. NO: 1 wherein the presence of any of the said polymorphic variations and the absence of a polymorphism outside of positions 2201, 2430, 2731, 3232, 3667, 4427, and 4956, is correlated with an absence of increased genetic susceptibility to breast or ovarian cancer resulting from a BRCA1 mutation in the BRCA1 coding sequence.[451]

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447. *In re* Prater, 415 F.2d 1393, 1395, 1398 (C.C.P.A. 1969).

448. *In re Musgrave*, 431 F.2d at 889-90 n.4 (citing Coulter, *supra* note 431 at 426).

449. *Id.*

450. *Ex Parte* Moser, 124 U.S.P.Q. 454, 455 (Pat. Off. Bd. App. 1959).

451. U.S. Patent No. 5,654,155 col. 65 l. 60-col. 66 l. 53 (filed Feb. 12, 1996).

The determination based upon an analysis and comparison of the sequenced genetic data, unlike the physical manipulations based upon observations in *Ex parte McNabb*, is a purely mental or an interpretive mental step.

The methods and materials of the patented DNA correlation claims go beyond the observation and markings in the insect control case of *Ex parte Kahn*, where no further interpretative skill or knowledge was required beyond recording and counting the actions of the insects. Rather, the claimed methods for patenting pre-existing genetic relationships involve a mental recognition of the significance of the relationship, the scientific determination, or even possibly, an aesthetic judgment that a correlation exists.[452]

Claims to the information involved in these correlations transcend the "mere thought" rule of *Kahn*, as relied upon in *Musgrave*. Not only is an operator not "merely thinking" in making these correlations, his actual *thought*, i.e., the determination or recognition itself is the object being claimed. Despite its' useful status within the technological arts, unlike the process for obtaining seismograms, patents on methods for determining genetic correlations for disease susceptibilities are "mental steps" and thus excluded from the categories of statutory subject matter.

A recent Federal Circuit case, *In re Comiskey*,[453] signals a revival of the doctrine, where the court considered whether a claim for "a method and system for mandatory arbitration involving legal documents, such as wills and contracts[,] . . . require[ing] resolution by binding arbitration of any challenge or complaint concerning any

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452. In fact, the assertion that the determination of the correlation is, in essence, a type of aesthetic judgment subject to different interpretations is illustrated by Denise Caruso:

> [A] consortium of scientists publishing findings that challenge the traditional view of how genes function. The exhaustive four-year effort was organized by the United States National Human Genome Research Institute and carried out by 35 groups from 80 organizations around the world. To their surprise, researchers found that the human genome might be a "tidy collection of independent genes" after all, with each sequence of DNA linked to a single function, such as a predisposition to diabetes and heart disease.
>
> Instead genes appear to operate in a complex network, and interact and overlap with one another and with other components in ways not yet fully understood. According to the Institute, these findings will challenge scientists to "rethink some long held views about what genes are and what they do."

Denise Caruso, *A Challenge to Gene Theory, a Tougher Look at Biotech*, N.Y. TIMES, July 1, 2007, at 3, *available at* http://www.nytimes.com/2007/07/01/business/yourmoney/01frame.html?_r=1.

453. *In re* Comiskey, 499 F. 3d 1365 (Fed. Cir. 2007).

unilateral document . . . [or] contractual document" was statutory subject matter.[454] The court stated that:

> Although the application's written description references "an automated system and method for requiring resolution through binding arbitration" and "a mandatory arbitration system through a computer on a network," claims 1 and 32 do not reference, and the parties agree that these claims do not require, the use of a mechanical device such as a computer.[455]

The court noted that standing alone, human thought processes, even if they have a practical application, are non-statutory (citing *Flook* for the proposition that even if used to solve a particular problem, if as a whole it covers methods for calculating with the use of a mathematical formula, the method is non-statutory).[456] The court established that neither claim 1 nor 32 required a machine or described a process of manufacture or a process for the alteration of a composition of matter, but rather claimed "the mental process of resolving a legal dispute between two parties by the decision of a human arbitrator" by conducting arbitration resolution for a contested issue and determining an award or decision for the contested issue, through a pre-determined arbitration system.[457] Comparing the claims to the unpatentable algorithms found in *Benson* and *Flook*, the court found the claims in the case non-statutory as they sought "to patent the use of human intelligence in and of itself."[458]

In re Bilski similarly revives the "mental processes" doctrine.[459] A claim was described as "a method of hedging risk in the field of commodities trading,"[460] and the claimed process allowed the transactions to involve options for buying and selling, "not limited to transactions involving actual commodities."[461]

The court concluded that, just as the claims in *Comisky* were for mental processes involved in arbitrating a dispute, the claimed process in *Bilski* was, as a whole, "directed to the mental and mathematical process of identifying transactions that would hedge risk."[462] These mental processes involve making calculations without

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454. *Id.* at 1368.

455. *Id.* at 1369.

456. *Id.* at 1378 (citing Parker v. Flook, 437 U.S. 584, 595 (1978)).

457. *Id.* at 1379.

458. *Id.*

459. *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008), *petition for cert. filed*, 77 U.S.L.W. 3442 (U.S. Jan 28, 2009) (No. 08-964).

460. *Id.* at 949.

461. *Id.* at 950.

462. *Id.* at 965.

requiring a computer or other device, mentally identifying the risk-reducing transactions and adding the post solution step of achieving the transaction.[463] A patent would pre-empt all applications of "hedging," even if confined to consumable commodities.[464] Thus, the claim was not drawn to patent eligible subject matter under § 101.[465]

A claim for a method which correlates genetic sequences to underlying medical conditions is analogous to the arbitration method of *Comiskey* and the risk-hedging method of *Bilski*. It similarly claims "a process of human thinking" which, when "standing alone, is not patentable even if the resulting claim has a practical application."[466] The claim of identifying individuals as being susceptible or not to a certain medical condition (i.e., possessing a particular genotype), by comparing data is essentially directed to a method of calculation and implementation of a formula. The process of identifying individuals having genetic susceptibilities does not require a machine for the comparison of the information, nor does it describe a process for the *alteration* of a composition of matter. Although the DNA fragment is "amplified" and sequenced, the process does not alter, transform, or reduce the information obtained by the process which merely identifies and extricates information rather than changing or altering an individual's DNA fragment. Indeed, if the process altered the information, the process itself would be unreliable. Cancers could either go undetected (false negatives) or be misdiagnosed (false positives) as a result of the isolated genetic information not faithfully representing the nucleotide sequence in the patient's genome.

Like the non-statutory algorithms of *Benson* and *Flook*, and the methods described in *Comiskey* and *Bilski*, claims to determinations or correlations, involving comparisons to the underlying data, the information of an individual's DNA fragment and a lack of polymorphic variation within that data, are similarly claims to the use of human intelligence in and of itself and constitute non-statutory mental steps.

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463. *Id.*

464. *Id.* at 965-66.

465. *Id.* at 966.

466. *In re* Comiskey, 499 F.3d 1365, 1377 (Fed. Cir. 2007).

IV. RECENT DEVELOPMENTS REGARDING THE SCOPE OF STATUTORY SUBJECT MATTER

Diamond v. Diehr was the last Supreme Court case to issue an opinion regarding the scope of statutory subject matter.[467] In 2005, however, the dissent in *Labcorp v. Metabolite*[468] raised the question of the scope of § 101 in considering whether a physician's correlation of elevated levels of homocysteine (an amino acid existing in the human body) to a deficiency of vitamin B, was a stated exception to patentable subject matter, a claim to a law of nature, natural phenomenon, or abstract idea.[469] Not having been raised by the lower courts, the question was left undecided on procedural grounds.[470]

Although the Court did not consider issues specific to computers or biotechnology, it is arguable that the dissenting opinion, stating that the question should have been decided and discussing the substantive issue, influenced the *Nuijten*, *Comisky*, and *Bilski* decisions, the first cases to address patentable subject matter following *Metabolite*. Their outcomes echo the rationales set forth in Justice Breyer's dissent.

The patentee in *Metabolite* argued that in Claim 13, the assaying, or testing step involved in making the correlation between the level of homocysteine in the blood and a vitamin B deficiency, was a transformative step.[471] Justice Breyer disagreed, arguing that the step did not transform the blood or any other matter, nor was the step inventive, as it could be done with any available test.[472] He also addressed the "concrete, tangible, and useful result" test of *State Street*, noting that the Court never authorized this particular standard, and, "if taken literally, the statement would cover instances where this Court has held to the contrary."[473] The dissent argued that the correlation was merely a natural process, a law of nature, mental steps, or processes–an instruction for physicians to compare numbers illustrative of an underlying and pre-existing scientific principle.[474] Thus, the dissent considered the underlying principle an abstract, intangible idea–a conclusion similar to those reached regarding the

467. Phillip McGarrigle & Vern Norviel, *Laws of Nature and the Business of Biotechnology*, 24 SANTA CLARA COMPUTER & HIGH TECH. L.J. 275, 286 (2008).

468. Lab. Corp. of Am. Holdings v. Metabolite Lab., Inc., 548 U.S. 124 (2006).

469. *See id.* at 132.

470. *Id.* at 132.

471. *Id.* at 134-35.

472. *Id.* at 136.

473. *Id.*

474. *Id.* at 136.

signal in *Nuijten*, or the non-statutory mental processes of the claims in *Comiskey* and *Bilski*.

Despite the Court's refusal to consider the case, the significance of the questions it raised as voiced by the dissent, suggested the need for clarification regarding the scope of patentable subject matter. A letter regarding such clarification was issued by the Commissioner of Patents, relying on former Supreme Court precedents and recent Federal Circuit decisions.[475] The Commissioner's letter stated that for a process to be considered statutory (i.e., falling within one of the four enumerated categories of § 101) it had to " (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing."[476] An example was provided to illustrate a method or process which would *not* qualify as statutory: "a claim that recited purely mental steps."[477] A patentable claim should positively recite the other statutory class (thing or product) to which it is tied (such as identifying the apparatus that accomplished the steps of the method) or positively identify the subject matter that is being transformed.[478] Finally, the letter noted that the Interim Guidelines for patentable subject matter would be revised based upon the outcomes of numerous pending cases on appeal at the Federal Circuit (such as *In re Bilski*), noting that the issue of subject matter patentability was evolving.[479]

These developments all have implications for claims to the information of isolated and purified DNA sequences, as well as claims to methods that include such sequences, especially if construed as reading on the informational content of the sequence. Clarified as pertaining to claims to intangible or embodied information, they are exceptions to patentable subject matter, analogous to the pre-existing, although recently discovered relationship between levels of homocysteine and vitamin B in a human body discussed in *Metabolite*. As previously discussed, a DNA sequence additionally falls outside the enumerated categories of statutory subject matter like *Nuijten*'s signal, or a sequence correlation to a genetic susceptibility, analogous to the methods in *Comiskey* and *In re Bilski*, all of which represent important precedents in considering the patentability of human DNA.

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475. *See* Memorandum from John Love, supra note 55.

476. *Id.*

477. *Id.*

478. *Id.*

479. *Id.*

Similar to the clarifications issued by the Patent Office which described the requirements for a process to be considered statutory subject matter, later confirmed in *Bilski*, claims involving the information of isolated and purified DNA sequences are not tied to any other statutory class, such as a particular apparatus. Nor is any underlying subject matter, such as an article or material transformed to a "different state or thing." These recent cases and developments within the USPTO therefore suggest the possibility that, should cases be brought regarding the statutory nature of DNA sequences or correlations between a claimed sequence and susceptibility to a medical condition, they would not meet the requirements to be considered patentable subject matter.

CONCLUSION

A specific and accurate characterization of what is *actually* being claimed is imperative in cases involving statutory subject matter. Examining the biological nature of DNA and the precise language of claims involving these sequences reveal that the only purpose or rationale underlying attempts to patent DNA sequences is to gain the exclusive use and control of the informational content, the disembodied information existing within, or embodied as, a molecular structure. Considering the statute, cases, and regulations governing the scope of statutory subject matter existing over the last 100 years, it should be recognized that human genetic material should not be considered patentable subject matter.

Instead, examining the precise scientific nature of DNA and DNA sequences defines these claims as simply covering information, intangible or embodied within a molecular structure. Described as "isolated" or "isolated and purified" sequences, they are simply, whether naturally occurring or existing outside the body, instructions for protein synthesis, analogous to algorithms involved in the workings of computer technology. As such, they exemplify specific exceptions to patentable subject matter as laws of nature or pre-existing scientific principles or truths. The Supreme Court and the Federal Circuit expanded the scope of statutory subject matter in cases dealing with computer technology, where mathematical principles or algorithms were applied in a manner which transformed an underlying object into a different state or thing. The information in human DNA is not similarly transformed by the technical processes of "isolation and purification." Thus DNA sequences should be held non-statutory laws of nature.

Not only do such sequences exemplify the laws of nature exception to statutory subject matter, they also do not fall within any of the four enumerated categories of patentable subject matter. Additionally, DNA sequences represent non-statutory printed manner, and are also subject to the "mental steps" doctrine, seemingly revived in *In re Comiskey*[480] and *In re Bilski*.[481] Correctly construed as claims to the intangible or embodied information of human DNA sequences, when considering the law governing patentable subject matter, claims to this human genetic material should be found non-statutory.

It is possible, however, that the Patent Office and the lower courts might retain their archaic characterization of the nature of human DNA as simply a static chemical, or an erroneously described "composition of matter," allowing for the continuing granting of patents on this information.[482] If this practice persists in the age of global biotechnology, DNA would continue to exist as commercially invaluable information when patented.[483]

This recognition of the true nature of claimed DNA sequences necessarily raises serious public policy questions. When a patent has been granted on the exclusive use of genetic information, the ability to use the information has been removed from the public domain. This practice arguably undermines the Constitutional objective to promote "the progress of science."[484] Whether the exclusive use of this information provides more benefits or harms has been extensively discussed and debated in the literature.[485] This is, however, irrelevant to the narrow question of whether or not the removal of this knowledge from the public domain is legal under the authority of the patent statute, as interpreted by the Supreme Court, the Federal Circuit, and the lower courts.

Due to the nature of patent litigation, the specific question regarding subject matter eligibility has little likelihood of being raised.[486] As one commentator has noted, patent examiners at the USPTO have few explicit grounds for rejecting a patent under § 101.

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480. *In re* Comiskey, 499 F.3d 1365 (Fed. Cir. 2007).

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

482. *See, e.g.*, *supra* notes 9-13 and accompanying text.

483. *See, e.g.*, GLOBAL GENOME, *supra* note 6; RAJAN, *supra* note 7.

484. *See* U.S. CONST. art. I, § 8, cl.8.

485. *See, e.g.*, Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUST. L. HEALTH L. & POL'Y 65 (2002); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987).

486. *See* Eileen M. Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN'S L. REV. 519, 520 (2006).

The issue of statutory subject matter is rarely noticed.[487] In actions for patent infringement in the federal district courts, the accused infringer can formally allege that the patent is invalid "on the basis of lack of patentable subject matter," or "the court [can] take notice[, sua sponte,] of the possible relevance of the issue to the litigation."[488] However, a study of litigated patent cases revealed that only 0.7% of the invalidated patents in the study were found invalid for falling outside of § 101 constraints.[489] There are a variety of explanations for this statistic, including the parties' potential unfamiliarity with the patentable subject matter doctrine, and that patent disputes often arise between similarly situated competitors who do not dispute the patenability of the subject matter.[490]

If the issue of DNA sequences as statutory subject matter is not addressed during patent examinations or litigation, this vital information's removal from the public domain, and the potential for its use, will continue. Aside from the issues discussed in this article, different grounds for challenging such patents might also emerge, including the constitutionality of removing information from the public domain. As an example, it is arguable that First Amendment concerns of denying access to information and restricting the freedom of thought are raised by the grant of these patents. Nevertheless, the protections of the Court might not recognize and legitimize the characterization of DNA sequences as *information*: an explicit exception to patentable subject matter as laws of nature, and outside the scope of the enumerated statutory categories. If this occurs, we will continue to rely upon social scientists and historians to consider the implications of privatizing the information and knowledge known as the genetic code.

487. *Id.* at 553.

488. *Id.* at 527.

489. *Id.* (citing John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208 tbl.1 (1998) (presenting data on the grounds for invalidity most frequently cited in their study of patent litigation)). The number stands in contrast to other statutory grounds such as novelty, 35 U.S.C. § 102 (2000), or obviousness, 35 U.S.C. § 103 (2000).

490. *Id.* at 528-29.