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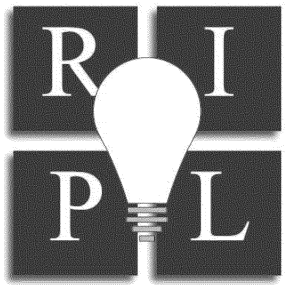

NATURE OR NURTURE: IS THERE A CASE BASIS FOR A JUDICIALLY CREATED 'PRODUCT OF NATURE' EXCLUSION? ARE GENES SOMEHOW DIFFERENT?

W. LESSER

ABSTRACT

The *Myriad Genetics* decision has rekindled the product of nature debate. This article analyzes legal decisions spanning the past century for products ranging from plants to man-made elements, which in sum provide guidance to the patentability of genes. The product of nature argument it is concluded confuses rather than clarifies patentability considerations. Patentability in the evaluated cases as well as for genes can be resolved more precisely under the utility, non-obviousness, disclosure, and enablement patentability requirements without a need for any additional judicially-created stipulation.

As regards genes, there is an additional dimension for consideration which in the case law and scientific literature is referred to as 'information', although the two groups do not use the term equivalently. Decisions involving complex compositions of matter cannot be treated the same way as simple chemical substances. This article argues that the information dimension of genes is an enablement and patent scope, not a patentable subject matter, issue. The appropriate scope will emerge over time as the science of genomics advances. In the interim it is proposed that the allowed scope err on the side of too limited rather than too broad.

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W. LESSER*

INTRODUCTION

A point identifies a location in space. Two points make a line, so we were told in introductory physics classes.[1] This article is interested in other kinds of points and the complex 'space' they delineate: the space which distinguishes non-patentable subject matter in the form of products of nature from those with sufficient human involvement to be potentially patentable. The 'points' are legal decisions and congressional interpretations spanning over eighty years which, this article argues, when evaluated in their entirety indicate that the 'product of nature' argument is both redundant and vague. The matters at hand can instead be resolved more precisely under the utility, novelty, and non-obviousness disclosure and enablement patentability requirements without a need for additional stipulation.[2]

This position is not new, and was espoused effectively in *Dennis v. Pitner*[3] back in 1939, but new technological options seem to have obscured old wisdom:

> The statements, 'the laws of nature,' 'the principles of nature,' 'the fundamental truths,' etc., are not patentable, have been oft repeated but seldom understandingly used. They have led to misunderstanding and much confusion, not limited to members of the bar. In fact, the words 'laws of nature,' 'principles of nature,' and 'fundamental truths' are all words of broad and also elastic meaning and are frequently used carelessly and without any attempt at refined distinctions.
>
> In fact, they have not been legally defined or defined with such accuracy as to permit of wide or safe application. Like the term

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 William Lesser's research focuses on the implications of agricultural biotechnology products on production costs and the size, structure, and geographic distribution of farming. He also concentrates on the costs, benefits, and structural implications of intellectual property—particularly patents—for plants, seed, and animals. His analyses include comparisons between the U.S., Europe, and developing countries. Professor Lesser worked on the application of intellectual property rights for the implementation of the Rio Biodiversity Convention at the International Academy of the Environment in Geneva, Switzerland, and he was the acting executive director of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), which is responsible for transferring new agricultural technologies to developing countries. He has advised the governments of Brazil, Indonesia, and Bangladesh, among others, on intellectual property matters and, in 2000, established the Cornell-in-India Agribusiness Executive Management Program. His other research interests include food distribution efficiency, technology transfer, and livestock marketing.

[1] ANTHONY BEDFORD & WALLACE FOWLER, ENGINEERING MECHANICS STATICS & DYNAMICS 6 (Prentice Hall, 3d ed. 2002).

[2] 35 U.S.C. §§ 101–103, 112 (2006).

[3] Dennis v. Pitner, 106 F.2d 142 (7th Cir. 1939).

> 'aggregation' they have been invoked indiscriminately by members of the patent bar to cover many kinds of defenses and often when counsel are desperately searching for even a paper defense. They are thus used as somewhat synonymous with 'general principles.'[4]

The underlying issue here is of course the *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office* ("*Myriad*")[5] decision, which reopened the product of nature debate by way of summary judgment invalidating fifteen claims in seven gene patents.[6] On appeal, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") reversed the district court's "decision that Myriad's composition claims to 'isolated' DNA molecules cover patent-ineligible products of nature under [s]ection 101 [of the Patent Act] since the molecules as claimed do not exist in nature."[7] Non-reversal would likely have led to the revocation of thousands of gene patents and patent ineligibility of compounds discovered in the wild, which constituted a majority of pharmaceutical product sales by value as well as many neutraceuticals and 'inventions' in many other areas of science.[8]

Although patents for unaltered genomic DNA were granted as early as 1982,[9] the product of nature debate reached an uneasy truce for genes and microorganisms with the U.S. Patent and Trademark Office's ("USPTO") position established in the Utility Examination Guidelines, granting patents for naturally-based products which were in a purified form not found in nature.[10] That position was overturned by *Myriad* and subsequently reversed on appeal.[11]

This article is not concerned with several aspects of the *Myriad* decision, which is to say matters regarding whether genes are indeed 'manufactures' or 'compositions of matter' in the sense of section 101 of the Patent Act.[12] More broadly, jurisdictional matters and the justification of the summary judgment decision are not specifically related to the product of nature issue, and the *Myriad* method claims are only indirectly so. Nor does this article attempt to assess the moral issues, as important as they are, regarding the patenting of parts of the human body. Rather the focus is specifically on the judicially-created 'product of nature' bar. Does it, or need it, exist? This analysis considers all areas of technology, but with particular attention given to genes.

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[4] *Id.* at 145.

[5] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 184, 238 (S.D.N.Y. 2010), *appeal filed* (Fed. Cir. Oct. 22, 2010).

[6] *Id.*

[7] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1334 (Fed. Cir. 2011) (*Myriad Appeal*).

[8] ANTHONY ARTUSO, DRUGS OF NATURAL ORIGIN: ECONOMIC AND POLICY ASPECTS OF DRUG DISCOVERY, DEVELOPMENT, AND MARKETING 4 (Hayworth Press, 1997).

[9] *See, e.g.,* Adrenocorticotropin-Lipotropin Precursor Gene, U.S. Patent No. 4,322,499 (filed Dec. 22, 1978) (issued Mar. 30, 1982).

[10] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

[11] *See Myriad,* 702 F. Supp. 2d at 181, 184, 238; *Myriad Appeal,* 653 F.3d at 1334.

[12] 35 U.S.C. § 101 (2006).

In part, the document under assessment here is the Amicus Curiae in Support of Neither Party filed by the United States Department of Justice ("DOJ").[13] Therein, while criticizing the *Myriad* decision for exclusion of the method claims and those composition claims reading to complementary DNA ("cDNA"), the brief does make a broad and detailed argument that naturally occurring DNA, whether purified or not, and as distinct from cDNA, is a product of nature and hence not patentable subject matter under the judicial interpretation of section 101.[14]

A not-inconsequential aspect of this broader debate over products of nature is the economic consequences of any decision. The market value of patented products is not a specific criterion of patentability,[15] but the enhancement of the economic incentive for investing in inventive activities underlies the U.S. patent system. One need only consider the authorization terminology in the Constitution: "To promote the Progress of Science and useful Arts . . . ."[16] As applied to products closer to nature, the Senate, when authorizing the Plant Patent Act of 1930, identified the intent as "remov[ing] the existing discrimination between plant developers and industrial inventors."[17] Intellectual property protection provided the breeder with a "financial incentive to enter upon this work"[18] while benefiting the public with lower initial prices as the investment can be recovered over multiple years instead of the one-to-three-seasons before competing suppliers can propagate unprotected new varieties.[19]

As always, patentable subject matter decisions involve a tradeoff between private incentives and the public costs of the partial monopoly rights granted.[20] In the case of products of nature, identifying a few possible components, are both central to life and hugely personal. However, the case history, reviewed in Part II, lacks intellectual symmetry, leading to a large number of inconsistencies in what is and is not allowed, creating the kind of regulatory uncertainty that is an anathema to investors. This article attempts to identify a coherent approach to 'products of nature' from the fragmentary case law.

In the case of *Myriad* however, there is the additional complexity of genes, which occupy dual states as 'physical products' and 'information'.[21] This article notes that there are multiple interpretations of what the 'informational' role of genes is, including a major difference between the interpretations of the district court's *Myriad* opinion and the Federal Circuit's *Myriad Appeal* opinion. This important issue is addressed in Part III.

The article is structured as follows. The following section reviews the *Myriad* and *Myriad Appeal* decisions and the related literature on products of nature

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[13] *See* Amicus Brief for the United States in Support of Neither Party, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 9-CV-4515) 2010 WL 4853320 [hereinafter Amicus Brief for the United States].

[14] *Id.* at 9–10.

[15] Stiftung v. Renishaw 945 F.2d 1173, 1180 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications.").

[16] U.S. CONST. art. I, § 8, cl. 8.

[17] S. REP. NO. 71-315, at 1 (1930).

[18] *Id.*

[19] *Id.* at 2.

[20] *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989).

[21] Myriad, 702 F. Supp. 2d 181, 184, 185 (S.D.N.Y. 2010).

decisions. Part II uses that case law to delineate a 'shape' containing products of nature, which, if followed, provides some clarity on patentable subject matter in this important area. Part III considers the additional 'dimension' of genes, that of information. Finally, conclusions are presented in Part IV.

I. *MYRIAD* GENETICS

A. Background and Decision

The Association for Molecular Pathology, a not-for-profit scientific society along with eighteen additional plaintiffs representing other not-for-profit groups and medical societies along with individual doctors and patients, sued the USPTO for summary judgment to dismiss fifteen claims in seven patents owned by Myriad Genetics and the University of Utah Research Foundation.[22] The claims related to two genes, Breast Cancer Susceptibility Genes 1 and 2 ("BRCA1" and "BRCA2") and alleles (variants or mutations) thereof, associated with a heightened susceptibility to a form of breast cancer and, less commonly, ovarian cancer.[23] The plaintiffs contended that the granted claims encompassed non-patentable subject matter and hence violated the Patent Act, the U.S. Constitution, and the First and Fourteenth Amendments of the U.S. Constitution.[24] Judge Sweet of the U.S. District Court for the Southern District of New York on March 29, 2010, granting the plaintiffs' motion for summary judgment in part, declared the claims-in-suit to be invalid.[25] On appeal, the Federal Circuit reversed the decision regarding the composition of matter claims but not for the process claims.[26]

The National Academy of Sciences estimated that the U.S. had granted approximately 33,000 gene-related patents, including patents covering about twenty percent of the genes in the human genome, through 2005, indicating that the consequences of the court's judgment for the fields of medicine and patent law are quite substantial.[27] A 2009 survey of high technology users of the patent system determined that use and importance was higher in biotechnology, which would include genomics, than for most other areas.[28] This article considers only the patent law issues, particularly those associated with section 101.[29]

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[22] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365, 370–76 (S.D.N.Y. 2009) (leading to the partial grant of summary judgment in *Myriad*).

[23] *Myriad,* 702 F. Supp. 2d at 184–85, 217.

[24] *Id.* at 186.

[25] *Id.* at 238.

[26] Myriad Appeal, 653 F.3d 1329, 1334 (Fed. Cir. 2011).

[27] COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, NATIONAL RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 101–02 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006).

[28] Stewart J.H. Graham, et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH L.J. 1255, 1293–94 (2009).

[29] *See* 35 U.S.C. § 101 (2006).

B. Claims-in-Suit

The fifteen claims-in-suit contained in the seven patents-in-suit are as follows: claims 1, 2, 5, 6, 7, and 20 of U.S. Patent No. 5,747,282 (the "'282 patent"); claims 1, 6, and 7 of U.S. Patent No. 5,837,492 (the "'492 patent"); claim 1 of U.S. Patent No. 5,693,473 (the "'473 patent"); claim 1 of U.S. Patent No. 5,709,999 (the "'999 patent"); claim 1 of U.S. Patent No. 5,710,001 (the "'001 patent"); claim 1 of U.S. Patent No. 5,753,441 (the "'441 patent"); claims 1 and 2 of U.S. Patent No. 6,033,857 (the "'857 patent").[30] These claims may be classified in two ways, 'composition' claims and 'method or process' claims.[31]

The composition claims can be best exemplified by claim 1 of the '282 patent, which reads, "[a]n isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2."[32] This claim addresses an isolated DNA molecule having a nucleotide sequence that decodes the BRCA1 protein.[33] The problem is that claim 1 could apply to other DNA sequences in addition to that identified as SEQ ID NO: 2 because many different DNA sequences can result in producing the same protein.[34]

Even broader is claim 6 of the '492 patent, which is directed to any DNA nucleotide encoding any mutant BRCA2 protein related to a predisposition to breast cancer.[35] This claim reads as follows: "[a]n isolated DNA molecule coding for a mutated form of the BRCA2 polypeptide set forth in SEQ ID NO: 2, wherein said mutated form of the BRCA2 polypeptide is associated with susceptibility to cancer."[36] Because of claim 6's broad wording, it extends and encompasses BRCA1/2 DNA obtained from a human being."[37]

The method or process claims can be represented by claim 1 of the '999 patent.[38] It reads as follows:

> [a] method for detecting a germline alteration in a BRCA1 gene, said alteration selected from a group consisting of the alterations set forth in Tables 12A, 14, 18, or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO: 1.[39]

This claim includes the process of identifying the existence of specific mutations in the BRCA1 gene through an analysis of the sequence of the BRCA1 DNA, RNA, or

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[30] Myriad, 702 F. Supp. 2d 181, 184, 238 (S.D.N.Y. 2010).
[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.* at 212–13.
[36] U.S. Patent No. 5,837,492 (filed Apr. 29, 1996).
[37] *Myriad,* 702 F. Supp. 2d. at 212–13.
[38] *Id.*
[39] *Id.* at 213.

cDNA made from BRCA1 RNA, which is taken from a human sample.[40] Particular attention here is focused on the composition claims, which apply to the product of nature issue.

C. Molecular Biology and Gene Sequencing

Evaluating the case decision requires some understanding of the structure and function of genes, and of the current practice of gene sequencing.[41] To that end, Judge Sweet dedicated multiple pages of his decision to an overview; here, a similar description will be attempted, but further abbreviated, with attention limited to complex organisms—i.e., those with cell nuclei, known as eukaryotes.[42]

From a nonscientific, functional perspective, genes are units of heredity contained in the chromosome and many of which produce, or encode, proteins essential for cell replication and for maintaining life functions.[43] In fact, the code for producing an individual protein is what is commonly meant by 'gene'.[44] Insulin and growth hormone, for example, are proteins produced by genes.[45] In practice, it is not the genes *per se* which confer inherited traits like eye color or disease susceptibility, but alleles.[46] Genes constitute a chemical compound or molecule, abbreviated as DNA, which is composed of four 'nucleotides' or 'bases,' described in shorthand as A, G, T, and C.[47] DNA typically exists in the form of the well-known 'double-helix' which represents the bonding of a base with only its complimentary base pair.[48] A typical multi-gene DNA molecule contains multiple distinct DNA segments and, hence, often can encode multiple proteins. More specifically, a DNA molecule is typically thousands of nucleotides long, but only two percent of the DNA is associated with the production of proteins (the coding regions), meaning that up to eighty or ninety percent has no known function and is sometimes referred to as 'junk' DNA.[49] There are roughly 25,000 human genes, and typically more plant genes.[50]

Protein encoding is accomplished by a gene 'unraveling' over the relevant coding section and an enzyme RNA polymerase is used to create a 'template' of the molecule, which is known as messenger RNA, or mRNA.[51] The copied sequence is initiated at

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[40] *Id.*

[41] *See* Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 44 U.C. DAVIS L. REV. 177, 188–93 (2010); Eric J. Rogers. *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19, 21–26 (2011); PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY: FUNDAMENTALS OF GLOBAL LAW, PRACTICE AND STRATEGY 243–46 (Oxford Univ. Press, 1999).

[42] *Myriad,* 702 F. Supp. 2d at 193–200.

[43] NEIL A. CAMPBELL, BIOLOGY 289 (Benjamin/Cummings Pub. Co., 4th ed. 1996).

[44] *Id.*

[45] *See* GABI NINDL WAITE & LEE R. WAITS, APPLIED CELL AND MOLECULAR BIOLOGY FOR ENGINEERS 264–65 (McGraw-Hill, 2007).

[46] CAMPBELL, *supra* note 43, at 249.

[47] *Id.* at 286.

[48] *Id.* at 285.

[49] Elizabeth Pennisi, *DNA Study Forces Rethink of What It Means to Be a Gene*, 316 SCIENCE 1556, 1556 (2007).

[50] MATT DEKISI & PETER JOHN CONIS, VIOLENT OFFENDERS: THEORY, RESEARCH, PUBLIC POLICY, AND PRACTICE 37 (Jones and Bartlett, 2008).

[51] CAMPBELL, *supra* note 43, at 300, 304.

the promoter and grows until reaching the stop codon or terminator DNA sequence.[52] In practice, genes often have complex systems of regulators and promoters so that the same DNA sequence may be 'read' in different ways, leading to multiple protein products.[53] The mRNA is then used in the production of the particular protein.[54] The production of mRNA removes introns and exons from the DNA coding sequence.[55] Introns in particular, are often longer than the mRNA itself.[56] The specific functions of introns and exons are complex and obscure, but as a first approximation in this simplified overview, they can be considered as unimportant materials to be removed as part of the production of mRNA.[57]

Considering now human involvement, DNA can be extracted from its cellular environment and, using specialized restriction enzymes, the particular segment of interest, such as a coding for a useful protein, can be excised.[58] This free-floating form of DNA is referred to as 'purified' DNA, in contradistinction to the naturally occurring or 'native' form.[59] Conversely, if the mRNA of interest can be isolated, the corresponding DNA may be produced using reverse transcription. The resulting molecules are known as complementary DNA, or 'cDNA', which is an exact copy of a coding region of the native DNA even if differing in physical form, i.e., excluding the introns.[60] One difference between the two is that with purified DNA is relatively stable, allowing for its use in biotechnological and diagnostic applications where native DNA would be unsuitable.[61] The term 'isolated DNA' is also sometimes used with parallels to cDNA, but the exact definition is unclear in the broader scientific literature.[62] *Myriad* suggested that "'isolated' DNA is a purified fragment of the entire native DNA in a gene.[63] The term 'isolated and purified' is also used in the *Utility Examination Guideline*.[64]

It should be noted that purified DNA along with cDNA have different genetic sequences from the native version, which sometimes leads to different chemical functionality or a distinct molecular shape. The distinct molecular shapes have the ability to alter the functionality.[65] The sensitivity of an organism to these differences can vary as well.[66] Human insulin as well as both porcine and bovine insulin, for example, differ slightly, but function equally well in the human body.[67] The same

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[52] *Id.* at 304.

[53] *Id.* at 317.

[54] *Id.* at 300.

[55] *Id.* at 315.

[56] David Weatherall, *On the Track of Genetic Disease*, NEW SCIENTIST, Apr. 5, 1984, at 32, 33.

[57] *Id.*

[58] CAMPBELL, *supra* note 43, at 370.

[59] Jennifer A. Camacho, *Myriad and the Patent-Eligibility of Genetic Inventions: What's the Matter Under 35 U.S.C. § 101?*, 11 INTELL. PROP. & TECH. L.J. 10, 13 (2011).

[60] CAMPBELL, *supra* note 43, at 374–75.

[61] Stephen H. Schilling, *DNA As Patentable Subject Matter and A Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 DUKE L.J. 731, 753 (2011).

[62] Turna Ray, *'Isolated DNA' Definition May be Biggest Barrier to Summary Judgment at Anti-Gene Patenting Hearing*, GENOMEWEB (Feb. 3, 2010), http://www.genomeweb.com/dxpgx/isolated-dna-definition-may-be-biggest-barrier-summary-judgment-anti-gene-patent.

[63] Myriad, 702 F. Supp. 2d 181, 230 n.53 (S.D.N.Y. 2010).

[64] *See* Utility Examination Guidelines, *supra* note 10, at 1093.

[65] CAMPBELL, *supra* note 43, at 375.

[66] *Id.* at 388.

[67] *Id.*

situation applies to natural alleles—many have no discernible effects, while others can greatly increase susceptibility to a disease—noting particularly the BRCA1/2 genes.[68]

As a result of the differences in functionality, a claim to a particular DNA sequence is likely to give too narrow a scope of protection.[69] Sometimes the terms 'innate variability' and 'degenerate' or 'redundant' are applied to the genetic code.[70] This situation conceptually parallels the case with chemical compounds.[71] In the chemical field, there are multiple categories of new inventions—new compounds, new compositions, etc.—with a characterized gene corresponding to the simplest case of a new chemical compound of known structure.[72] Again, like genes for which there are multiple DNA sequences for producing the same protein, chemical inventions will not consist of a single compound, but rather a group of compounds having common structural features with the same end use.[73] "It will be the task of the inventor in the research laboratory to synthesize sufficient compounds to form an idea of which compounds will work and which will not, and that of the patent agent to decide in consolation with the inventor what the scope of the claimed invention should be."[74]

DNA sequences producing an identified protein with known uses, or sequences associated with a particular disease, have multiple and evolving uses.[75] The protein itself can have markets, such as human insulin manufactured through inserting the human insulin gene into a bacteria like *E. coli*.[76] A gene inserted into a plant can provide useful new attributes; *Bacillus thuriengiensis* ("*Bt*") is one such successful agricultural application.[77] In animals as well as plants, it can be desirable to limit gene expression; agricultural applications of this antisense technology include methods for delaying ripening of fruits and vegetables.[78] A 'probe' which bonds with a target gene indicates heightened susceptibility to a specific disease while the genetic material provides the option for gene repair in the evolving field of gene therapy.[79] Numerous other applications exist and are evolving leaving little question of the potential utility of DNA sequences.[80]

The preceding description of genes also applies to their physical attributes. In Professor Philip Grubb's view, when DNA sequences are patented, "the emphasis has always been on the protein, with the DNA or gene seen simply as a means for the protection of the product of interest."[81] Additionally, there is an informational component; "DNA sequences are not simply molecules, they are information.

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[68] *Id.* at 349.

[69] GRUBB, *supra* note 41, at 243; Diana Sheiness, *Patenting Gene Sequences*, 78 J. PAT. & TRADEMARK OFF. SOC'Y, 121, 124 (1996).

[70] *Id.* at 122–23.

[71] *Id.* at 123.

[72] *Id.* at 123–24.

[73] Sheiness, *supra* note 69, at 124.

[74] GRUBB, *supra* note 41, at 194.

[75] Sheiness, *supra* note 69, at 124.

[76] CAMPBELL, *supra* note 43, at 388.

[77] CLIVE JAMES, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2010 217 (2010) (showing 2010 plantings of Bt-enhanced crops exceeded 26 million hectares).

[78] CAMPBELL, *supra* note 43, at 388.

[79] *Id.* at 386–87.

[80] *Id.* at 385.

[81] GRUBB, *supra* note 41, at 246.

Knowing the DNA sequence for the genome of an organism provides valuable scientific information that can open doors to future discoveries."[82]

Again, in Grubb's words, "[t]he situation becomes somewhat different when the focus of attention switches to the gene, particularly if it is discovered before the protein it encodes, and before the specific function of the protein is known."[83] Beyond the relatively few known cases where an inheritable disease susceptibility can be associated with a single gene or genes—note again the BRCA1 and BRCA2 genes—most inheritable diseases are associated with several genes having a possible environmental trigger.[84] Under those circumstances, researchers are motivated to protect the information as it evolves from projects and before a specific utility is identified.[85] Indeed, such information has, using Eisenberg's terminology, "immediate commercial value" while the commercial value of a template for a specific protein is "remote and speculative."[86] Eisenberg goes on to emphasize that the current technology of high-throughput DNA sequencing has generated thousands of sequences with, at present, little more than research value.[87]

Rogers identifies several sources of these immediate commercial values as revealing, which include:

- Gene function based on the sequence of amino acids and the predicted protein encoded,
- Multiple properties such as potential binding partners, enzyme activity, and sub-cellular compartment localization,
- Detailed biological information, including molecular form of the DNA, its derivative RNA, and the gene products,
- When, where and what causes the gene expression based on DNA sequences outside the coding regions, and
- Evolutionary history of the gene, its gene family and its origin species. [88]

All the preceding implies that there is no one, simple, definition of a 'gene'. Rogers indeed proposes three distinct definitions of a gene as a DNA segment that: (1) contributes to an inheritable phenotypic characteristic; (2) contributes to phenotype or function; and (3) reveals an 'image' of a DNA-derived molecule that is hypothesized to exist and function. [89]

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[82] Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMERY L. J. 783, 786–87 (2000).

[83] GRUBB, *supra* note 41, at 246.

[84] Steve Olson, *Making Sense of Tourette's,* 305 SCI. 1390, 1391 (2004).

[85] *Id.*

[86] Eisenberg, *supra* note 82, at 788.

[87] *Id.* at 788–89.

[88] Rogers, *supra* note 41 at 25–26.

[89] *Id.* at 22.

Definition one is described as the earliest definition preceding the discovery of DNA so that it is a purely conceptual definition.[90] With the discovery of the molecular structure of DNA in 1953, definition one was changed into the form of definition two incorporating the understanding that genes do indeed have a physical form and location, which is in the chromosome.[91] These definitions specify that a gene has an associated phenotype, which implies a known function.[92] Definition three applies to sequence data, such as produced by high-throughput screening, lacking functional information.[93] For that reason, it is not possible to know if the entirety of a gene has been identified and identified correctly, rather than a fragment or distortion of it.[94] Thus, Rogers uses the term 'image' to distinguish from a real molecule.[95] Given this ambiguity, Rogers rejects any use of the term 'gene', selecting in its place 'a DNA sequence'.[96] The terminology use here is not so scrupulous.

Related to the three definitions of a gene, Calvert and Joly specify three operational levels: molecular (i.e., biochemical function of the gene), biological (i.e., the biological process within which the expressed protein contributes), and the entire organism (i.e., the role played by the expressed protein).[97] They connect the complexities associated with gene expression—including "overlapping genes, genes within genes, and genes which spill over the boundaries for the chromosomes[98]—with the difficulty of defining a gene. "These diverse understandings of a gene show that the legal reduction of a gene to a chemical compound can no longer be supported in the context of the current practices of the scientific community."[99] As stated in *Amgen v. Chugai Pharm. Co.*[100] "[a] gene is a chemical compound, albeit a complex one."[101]

From this highly simplified overview, several conclusions relevant to the product of nature debate can nonetheless be made and include the following:

- 'Native' and 'purified' DNA are physically and chemically distinct (native DNA for one thing does not exist in a free floating form) so that a claim reading to purified DNA gives the patent owner no rights over naturally occurring DNA. An individual's genes are not patentable. The term 'isolated' DNA is not commonly used in the scientific literature but is applied in regards to gene patents where it corresponds to 'isolated and purified' DNA strains.

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[90] *Id.* at 22–23.
[91] *Id.* at 23.
[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.* at 26.
[97] Jane Calvert & Pierre-Benoit Joly, *How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA*, 50 SOC. SCI. INFO. 1, 11 (2011).
[98] *Id.*
[99] *Id.*
[100] Amgen v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991).
[101] *Id.* at 1206.

- Despite these chemical and physical distinctions, the underlying structure of the purified DNA, and much of its utility (i.e., probes), is derived directly from nature.

- While the coding regions are copied from nature, the resulting products may not be identical to the natural ones, and there is no general way to determine if the differences affect functionality. The same situation applies to natural variations (alleles).

- Multiple genes can produce the same or similar proteins meaning claiming a single DNA sequence may provide too narrow a scope of protection. Claiming multiple sequences or the protein *per se* though raises enablement issues.

- Many of the issues with patenting genes have direct parallels with patenting chemical compounds, as they are treated under patent law, but genes are complex, redundant living organisms so there is more innate variability than typically associated with chemical compounds.

- Genes exist as both tangible products and sources of information, the latter case applying particularly when the protein(s) coded for and/or their use have not been identified.

- Judge Sweet in *Myriad* however uses the term 'information' distinctly from the preceding, leading to a different outcome.

D. History of the Invention

The initial indication of the existence of a breast cancer-linked gene appeared in a landmark paper by Dr. King in 1990, but it was un-sequenced and identified only as being in the 'region of chromosome 17.'[102] A subsequent founder of Myriad Genetics, Dr. Skolnick, took an interest and provided the insight of identifying and linking the Utah Mormon Genealogy with the Utah Cancer Registry to provide the large data set required for a statistical program for gene mapping.[103] The Registry allowed the identification of communities with high prevalence of certain kinds of breast cancer, while the careful genealogical records maintained by Mormons provided intergenerational linkages for following the transmission of susceptibility. Even so, considerable effort and ingenuity are required to pinpoint the implicated gene or genes.[104] Subsequently, working with Dr. King, the National Institutes of Health, and utilizing venture capital funding, the BRCA1 and BRCA2 genes were sequenced in the 1990s.[105]

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[102] Myriad, 702 F. Supp. 2d 181, 201 (S.D.N.Y. 2010).
[103] *Id.*
[104] *Id.* at 201–02.
[105] *Id.*

E. Case Synopsis Regarding Statutory Subject Matter

1. The Myriad *Decision*

Quoting from Judge Rich's opinion of *In re Berg*,[106] Judge Sweet notes that determinations regarding the three patentability requirements of novelty, utility, and statutory subject matter are separate and distinct.[107] "Because it is undisputed that the claimed compositions and methods [in *Myriad*] possess utility,[108] the sole task of this Court is to resolve whether the claimed compositions and methods constitute statutory subject matter or fall within the judicially created products of nature exception to patentable subject matter."[109] Here, the focus will remain directly on the product of nature issue rather than whether it is patentable subject matter under section 101.[110] Any such non-statutory exception must fit into the "laws of nature, natural phenomenon, or abstract ideas" bars from *Chakrabarty*.[111]

First, Judge Sweet rejected the defendant's arguments to dismiss the plaintiffs' claims.[112] Those arguments were based on a granted patent's presumption of validity, the USPTO's policy of granting patents for purified compounds sourced from nature, and an attestation that invalidating the patents would involve an unconstitutional taking.[113] The unconstitutional takings argument was found unpersuasive in light of the many patents invalidated over time. And while section 282 does establish a presumption of validity, the Federal Circuit in *Arnold P"ship v. Dudas*[114] had previously required no deference to the USPTO's legal determinations.[115]

The USPTO's sole published position on the patentability of genes is contained in its Utility Examination Guidelines.[116] A patent claim directed to an isolated and purified molecule [i.e., a gene] is eligible for a patent because that DNA molecule does not exist in that isolated form in nature, even though it has the same sequence as a naturally occurring gene.[117]

With regards to the product of nature issues, Judge Sweet cites *American Fruit Growers v. Brogdex*[118] to emphasize that "a new or distinctive form, quality, or property" was required for a naturally-occurring article to become an article of manufacture.[119] Similarly in *Funk Brothers*[120] the patent holder "did not create a state of inhibition or of non-inhibition in the bacteria. Their qualities were the work

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[106] *See In re* Berg, 596 F.2d 952, 960 (C.C.P.A. 1979).
[107] *Myriad,* 702 F. Supp. 2d at 219.
[108] *Id.* at 219–20.
[109] *Id.*
[110] *Id.*
[111] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).
[112] *Myriad,* 702 F. Supp. 2d at 220.
[113] *Id.* at 220–23.
[114] Arnold P'ship v. Dudas, 362 F.3d 1338, 1340 (2004).
[115] *Myriad,* 702 F. Supp. 2d at 221.
[116] *Id.* at 220; *see also* Utility Examination Guidelines, *supra* note 10, at 1092.
[117] *Myriad,* 702 F. Supp. 2d at 224; Utility Examination Guidelines, *supra* note 10, at 1092.
[118] Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931).
[119] *Myriad,* 702 F. Supp. 2d at 222.
[120] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 128–31 (1948).

of nature. Those qualities are of course not patentable."[121] Other cases distinguishing naturally occurring products from manmade ones, and the sufficiency of purity included *Diamond v. Chakrabarty*[122] and *General Electric v. De Forest Radio*.[123] These and other prominent product of nature cases are reviewed in detail in Part II.

Myriad's defense relied in part on *Parke-Davis & Co. v. H.K. Mulford*,[124] which upholds a patent for isolated adrenaline, a purified natural product. [125] Judge Sweet, however, characterized *Parke-Davis* as a novelty and not a patentable subject matter question, describing Judge Hand's oft-repeated statement, "[b]ut, even if it were merely an extracted product without change, there is no rule that such products are not patentable," as dicta.[126] "The distinction between considerations of novelty and patentable subject matter similarly undermines *Myriad's* reliance on *Bergstrom*[127] and *In re Kratz*,[128] both of which presented issues of novelty and anticipation rather than the question of patentable subject matter."[129] Finally, while Myriad's council saw *Merck & Co. v. Olin Mathieson Chem. Corp*.[130] as supporting the patentability of purified products (in this case vitamin B_{12}), Judge Sweet found the opposite.[131] The development of vitamin B_{12} was more than a "mere advance in the degree of purity of a known product."[132]

On these bases, Judge Sweet concluded that the purification of a natural product, absent something more, "cannot transform it into patentable subject matter."[133] He then considered whether the claimed "isolated" genes exhibited any markedly different characteristics.[134] And here again, his and Myriad's perceptions differed.[135] Myriad's counsel argued that genes should be treated like other chemical compounds for patent eligibility purposes and that the claimed DNA is "markedly different" from the natural DNA.[136] Judge Sweet, however, took the view that DNA is not like other chemical compounds due to their informational content.[137] And that information encodes the primary biological function of DNA, "directing the synthesis of other molecules in the body—namely, proteins."[138]

Judge Sweet rejected *Myriad's* contention that the comparison should be applied to the differences between isolated and native DNA, and not their similarities.[139] Rather, "[t]he proper comparison is between the claimed isolated DNA and the

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[121] *Id.* at 130.
[122] Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980).
[123] Gen. Elec. Co. v. De Forest Radio Co. et al., 28 F.2d 641, 647 (3d Cir. 1928).
[124] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911).
[125] *Id.* at 114.
[126] *Myriad,* 702 F. Supp. 2d at 225.
[127] *In re* Bergstrom, 427 F.2d 1394, 1395 (C.C.P.A. 1970).
[128] *In re* Kratz, 592 F.2d 1169, 1173 (C.C.P.A. 1979).
[129] *Myriad,* 702 F. Supp. 2d at 226.
[130] Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1957).
[131] *Myriad,* 702 F. Supp. 2d. at 227.
[132] *Merck*, 253 F.2d at 164.
[133] *Myriad,* 702 F. Supp. 2d at 227.
[134] *Id.* at 227–28.
[135] *Id.* at 228.
[136] *Id.*
[137] *Id.*
[138] *Id.*
[139] *Id.* at 229.

corresponding native DNA, and the presence or absence of chromosomal proteins merely constitutes a difference in purity that cannot serve to establish subject matter patentability."[140] More specifically, Judge Sweet repeatedly turned aside Myriad's statements about the physical differences of native DNA from its claimed isolated DNA by emphasizing that those differences are insufficient to achieve a 'markedly different' status.[141]

For Judge Sweet, the key to this difference is not physical but functional. "However, the basis for this utility is the fact that the isolated DNA possesses the identical nucleotide sequence as the target DNA sequence."[142] And "the purification of native DNA does not alter its essential characteristic—its nucleotide sequence—that is defined by nature and central to both its biological function within the cell and its utility as a research tool in the lab,"[143] making reference to *Funk Bros.*[144] In conclusion he decides that, "[b]ecause the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under [section] 101."[145]

This decision appears to be based heavily on two interpretations: (1) that the 'information' dimension of genes is their template for encoding primarily proteins, a different use of the term "information" from that of many researchers who apply it to non-sequenced genes or those encoding for unknown proteins or those lacking a known use; and (2) defining 'markedly different' as between the native and claimed isolated DNA in terms of the unaltered functionality from the native DNA as regards its coding for a particular protein or a basis for serving as a disease probe.[146] Because there is none, at least in the somewhat static and mechanical world of Judge Sweet's perception of gene function, the Myriad patents-in-suit are unpatentable products of nature.[147] The appellants took strong exception to this position, arguing that "*Chakrabarty* did not pronounce or apply a *legal* standard that an invention must be 'markedly different' from a naturally occurring substance in order to be patent-eligible. Rather, the Court used 'markedly different characteristics' to describe a *factual* 'contrast' between the particular bacterium in [*Chakrabarty* and] *Funk Bros.*"[148]

The *Myriad* method claims are directed to a different dimension of section 101 patentability analysis.[149] They were rejected as mere data gathering, or unspecified methods because they are "directed only to the abstract mental process of 'comparing' or 'analyzing' gene sequences."[150] Unsurprisingly, the appellants contest this view,[151] arguing that Myriad's detailed DNA tests require the extraction and processing of human blood or tissue samples and are therefore 'transformative' in the *Bilski* sense.

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[140] *Id.* at 229–30.
[141] *Id.* at 230–31.
[142] *Id.* at 231.
[143] *Id.*
[144] *Id.*; *see also* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948).
[145] *Myriad,* 702 F. Supp. 2d at 232.
[146] *Id.* at 229–32.
[147] *Id.* at 232.
[148] Brief for the Appellants at 41, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, (S.D.N.Y. 2010) (No. 9-CV-4515) 2010 WL 4853320.
[149] *Myriad,* 702 F. Supp. 2d at 233.
[150] *Id.* at 234.
[151] Brief for the Appellants, *supra* note 148, at 55–56.

Hence, the claims are patentable subject matter.[152] In any case, this is not a product of nature issue, although it conceivably could otherwise be unpatentable subject matter as specified in *Chakrabarty*.[153]

2. U.S. Amicus Curiae Brief

"The extent to which basic discoveries in genetics may be patented is a question of great importance to the national economy, to medical science, and to the public health." This was the justification for the amicus brief submitted by the DOJ.[154] The amicus brief, which focuses on the composition claims but not the method claims, argues for limiting the scope of the *Myriad* decision, particularly allowing claims for: (1) engineered molecules such as cDNA and (2) isolated molecules whose value derives from the information-encoding capacity of DNA.[155] However, "genomic DNA merely isolated from a cell in the human body" is not a human-made invention and hence is not patent-eligible.[156]

cDNA, along with vectors, recombinant plasmids, chimeric proteins, etc., is a fruit of the manipulation of genetic material, and will "almost invariably be patent-eligible subject matter. These molecules generally do not occur in nature, but are instead the synthetic results of scientists' manipulation of the natural laws of genetics."[157] Particular note is made of claim 2 of the '282 patent.[158] The distinction is revealed in the patent wherein the MOLECULE TYPE in SEQ ID NO: 1 (claim 2) is identified as 'cDNA' while the MOLECULE TYPE in SEQ ID NO: 2 (claim 1) is referred to as "protein (xi)". On that basis, identifying from the list of claims-in-suit, the list is as follows:

	CLAIM NUMBER		
Patent	Isolated DNA	cDNA	Method
'282	1,5	2, 6, 7	20
'492	1, 6	7	
'473		1	
'999		1	
'001			1
'441			1
'857			1, 2

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[152] Bilski v. Kappos 130 S. Ct. 3218, 3226 (2010).

[153] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[154] Amicus Brief for the United States, *supra* note 13, at 1. As part of the section 101 analysis the Amicus Brief proposes a somewhat quixotic 'magic microscope' test which is not explored here.

[155] *Id.* at 9–11.

[156] *Id.* at 17–18.

[157] *Id.* at 14–15.

[158] *Id.* at 14. Claim 2 of the '282 patent reads: "The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO: 1." U.S. Patent No. 5,747,282 (filed June 7th, 1995).

According to the U.S. Department of Justice, only four claims in two patents (the '282 and '492 patents) are true product-of-nature claims, and are, thus, unpatentable.[159]

3. The Myriad Appeals *Decision*

As noted, the appellate decision reversed the district court's decision declaring the un-patentability of the claims.[160] The Federal Circuit made short shrift of Judge Sweet's analysis on the issue of patentable subject matter.[161] The court noted that:

> the Supreme Court has drawn a line between compositions that, even if combined or altered in a manner not found in nature, and compositions that human intervention has given 'markedly different' or 'distinctive' characteristics. Applying this test to the isolated DNAs in this case, we conclude that the challenged claims are drawn to patentable subject matter because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature . . . . [I]solated DNA is not purified DNA . . . . Thus, when cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity.[162]

The informational context is similarly disposed of quickly. The court noted that:

> [p]laintiffs argue that because the claimed isolated DNAs retain the same nucleotide sequence as native DNAs, they do not have 'markedly different' characteristics. This approach, however, looks not at whether isolated DNAs are markedly different—have a distinctive characteristic—from naturally occurring DNAs, as the Supreme Court has directed, but at one similarity: the information content . . . . We disagree, as it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit. Uses of chemical substances may be relevant to the non-obviousness of these substances or to method claims embodying those uses. The claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and *their informational content is irrelevant* to that fact.[163]

This view suggests that *any* physical or chemical structural distinction between isolated and native DNA is sufficient to establish the isolated DNA as patentable subject matter.[164] It is similar to the Plant Patent Act in this regard. At the same

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[159] Amicus Brief for the United States, *supra* note 13, at 32.
[160] Myriad Appeal, 653 F.3d 1329, 1334 (Fed. Cir. 2011).
[161] *See id.* at 1342.
[162] *Id.* at 1351–52 (citations omitted).
[163] *Id.* at 1353 (emphasis added).
[164] *Id.* at 1349–50.

time, the projected understanding of the chemistry and physics world view is a simple linear one; DNA is pure and is simply a chemical compound.[165] Any other attributes of the DNA are subsidiary to its being a compound. Thus, the information dimension of DNA is subordinated to being a use of the compound, which situation is irrelevant to the physical attributes of the isolated DNA, which distinguishes it as patentable subject matter. This issue is considered again when considering the scope of the protection in Part III. First, we consider the concurrences in-part by Judges Moore and Bryson, and the dissent in-part by Judge Bryson.

Judge Moore concurs with the majority regarding the potential patentability of isolated DNA and of cDNA in particular.[166] What troubles him are the broader claims like claims 1 and 5 from the '282 patent.[167] "These include claims encompassing both the isolated full length gene sequence, which are thousands of nucleotides, and claims to shorter isolated DNA strands, with as few as fifteen nucleotides, whose nucleotide sequence is found on the chromosome."[168]

For Judge Moore, mere differences in chemical structure of any isolated DNA may be insufficient for he applies the 'markedly different' test from *Chakrabarty*.[169] Shorter strands, for him, pass this test for they "have markedly different properties which are directly responsible for their new and significant utility."[170] Moore believes "small, isolated DNA fragments are patentable subject matter."[171] Longer strands—"genus claims" like claim 5 of the '282 patent— on the other hand are a distinct matter as they can encompass the entire isolated gene sequence.[172] As such, the "chemical and structural differences in an isolated DNA sequence which include most or all of a gene do not clearly lead to significant new utility as compared to nature."[173] Judge Moore continues to explain that "[d]espite the literal chemical difference, the isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature, namely to act as a gene encoding a protein sequence."[174] In the end, he did not wish to go against established expectations and property rights, and "these settled expectations tip the scale in favor of patentability."[175]

Judge Bryson, dissenting in part, was not so deferential, although he does concur with the majority decision regarding the cDNA claims.[176] For him, as with Judge Moore, the issue is the claims to the BRCA genes such as claim 1 of the '282 patent.[177] That claim "covers a truly immense range of substances from the cDNA that is 5914 nucleotides long to the isolated gene that contains more than 120,000 nucleotides."[178] "Included in that set are many important molecular variations to the

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[165] Amgen v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991).
[166] *Myriad Appeal,* 653 F.3d at 1358.
[167] *Id.* at 1364.
[168] *Id.*
[169] *Id.* at 1365.
[170] *Id.*
[171] *Id.*
[172] *Id.* at 1366.
[173] *Id.*
[174] *Id.* at 1367.
[175] *Id.*
[176] *Id.* at 1373.
[177] *Id.* at 1374.
[178] *Id.* at 1376.

BRCA1 gene that Myriad had not yet discovered and could not have chemically described."[179] Claim 5 of the same patent is "breathtakingly broad", "so broad that it includes products of nature (the BRCA1 exons) and portions of other genes."[180] "The naturally occurring genetic material, thus, has not been altered in any way that would matter under the standard set forth in *Chakrabarty*. For that reason, the isolation of the naturally occurring genetic material does not make the claims to the isolated BRCA genes patent-eligible."[181]

Neither Judges Moore nor Bryson raise the information issue, but both concur with the patent ineligibility of the method claims due to an attempt at "claim[ing] only abstract mental processes."[182] However, knowledgeable observers have suggested the method claims "would have been upheld if there was another step, such as sequencing the genes, in addition to just mental steps."[183]

4. Conclusions from the Myriad *Cases*

Through two court decisions and an amicus brief, there is concurrence on the patentability of the cDNA claims, and the exclusion of the method claims, but on what appears to be more claim terminology than substance. The contentious issue then is over the 'broad' gene claims (claims 1 and 5 for the '282 patent and claims 1 and 6 for the '492 patent), although the terms used are different. For Judge Sweet, the matter is 'information,' while Judges Moore and Bryson are concerned with the overly broad claims.[184] Only Judge Bryson actually uses the term 'products of nature.'[185] This sounds like more of a disclosure issue, something the majority in the appellate case rejects.[186] This article argues later that the pivotal issue of gene patents is indeed claim scope, but it first delves further into the product of nature matter, for all subject matter and not genes only.

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[179] *Id.*

[180] *Id.* at 1379.

[181] *Id.* at 1378.

[182] *Id.* at 1373.

[183] Andrew Pollack, *Ruling Upholds Gene Patent in Cancer Test*, N.Y. TIMES BUS. DAY, (July 29, 2011), http://www.nytimes.com/2011/07/30/business/gene-patent-in-cancer-test-upheld-by-appeals-panel.html.

[184] *Myriad Appeal,* 653 F.3d 1329.

[185] *Id.* at 1375.

[186] *Id.* at 1354. ("The issue before us is patent eligibility, not the adequacy of the patents' disclosure to support particular claims.").

II. PAST RULINGS OF WHAT IS AND WHAT IS NOT A PRODUCT OF NATURE: PHYSICAL PRODUCTS

A. Non-Patentable Products of Nature

1. Naturally-occurring Plants

Plants found in an uncultivated state are not eligible for a patent.[187] Specifically, the Senate Report of the Plant Patent Act states that the committee has "eliminated from the scope of the bill those wild varieties discovered by the plant explorer or other person who has in no way engaged either in plant cultivation or care and who has in no other way facilitated nature in the creation of a new and desirable variety."[188]

The exclusionary wording quoted above was, however, not added until after 1954 by an amendment following *Ex parte Foster*,[189] which excluded the patenting of a seedling discovered in the wild by a professional plant cultivator.[190] While this ban is specific and clear it applies to an extreme case with no human involvement.

2. Combinations of Naturally-occurring Microorganisms

In the oft-quoted *Funk Bros.* case,[191] the patent-holder Bond's invention applied to rhizobium, a soil bacterium which colonizes nodules on the roots of leguminous plants giving them the ability to 'fix' atmospheric nitrogen into the soil.[192] However, none of the six rhizobium species will function with all leguminous plants so that multiple species must be used to inoculate an assemblage of legumes.[193] It was soon evident that mixing different species of rizobium bacteria for broader application led to an inhibitory effect rendering each species less effective.[194] As a result, farmers

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[187] 35 U.S.C. § 161 (2006) ("Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title."); *see also Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443, 447 (B.P.A.I. 1985) (noting that the Plant Patent Act applies only to plants which can be asexually propagated); 35 U.S.C. § 161 (inferring that the relevance of the patentability of classes of plants to the issue of products of nature is not affected by the means of propagation of those plants). Section 101 protection was extended to sexually propagated plants in *Hibberd* with no reference to the products of nature issue beyond their resolution for plants in the Plant Patent Act. *See Ex Parte Hibberd*, 227 U.S.P.Q. at 447.

[188] 37 C.F.R. § 1.162 (2011) (stating that if the applicant plant is a newly found plant, an oath or declaration is required that it was found in a cultivated state); S. REP. NO.71-315 at 7 (1930).

[189] *Ex parte* Foster, 90 U.S.P.Q. (BNA) 16 (B.P.A.I. 1951).

[190] *Id.* at 18.

[191] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

[192] *Id.* at 129.

[193] *Id.* at 129–31.

[194] *Id.* at 130.

had to use a selection of species to inoculate a range of leguminous crops; a cost and management burden for them as well as dealers and distributors.[195]

That was the case prior to Bond's efforts, which permitted him to identify and select some strains of rizobium species which proved not to inhibit the other species. As a result, a farmer needed but one package of rizobium for any number of crops, and the product was a "prompt and substantial commercial success."[196]

Difficulties for Bond began in a patent infringement suit under which the district court invalidated certain product claims, only to have the decision reversed by the Federal Circuit before reaching the Supreme Court.[197] Justice Douglas delivering the opinion of the Court reversed the decision of the Federal Circuit, noting famously:

> Bond does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.[198]

The Court continues to hold that Bond's claims were "no more than the discovery of some of the handiwork of nature and hence is not patentable."[199] "Even though it may have been the product of skill, it certainly was not the product of invention."[200] "All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough."[201]

In a thoughtful concurrence, Justice Frankfurter does recognize Bond's combination of species and strains as potentially patentable; "Bond"s mixture does in fact have the new property of multi-service applicability."[202] However, Justice Frankfurter also states:

> Bond makes no claim that Funk Brothers used the same combination of strains that he had found mutually compatible. He appears to claim that since he was the originator of the idea that there might be mutually compatible strains and had practically demonstrated that some such strains exist, everyone else is forbidden to use a combination of strains whether

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[195] *Id.* at 128–29.
[196] *Id.* at 136.
[197] *Id.* at 128.
[198] *Id.* at 130.
[199] *Id.* at 131.
[200] *Id.* at 132.
[201] *Id.*
[202] *Id.* at 135.

> they are or are not identical with the combinations that Bond selected and packaged together.[203]

This excerpt illustrates that Frankfurter's concurrence is based on section 112 specification first paragraph grounds and not Douglas' section 101 rejection.

3. Tungsten from Gen. Elec. v. De Forest Radio

General Electric ("GE") was the assignee of the patented invention of a ductile form of tungsten suitable for use as a filament in lights and vacuum tubes.[204] The defendants, De Forest Radio, which manufactured the tubes, and Robelen Piano Co, a retailer of De Forest Radio products, were accused of infringement.[205] The claim of relevance to the natural products issue was claim 26. Claim 26 disclosed "[s]ubstantially pure tungsten having ductility and high tensile strength" and was considered to be the broadest of 34 total patent claims.[206] Of those 34 claims, only six were in suit.[207] While claim 26 does not claim 'tungsten' *per se*, the patent reads to "Tungsten and Method of Making the same" and claim 28 (also in suit) claims "a form of tungsten metal pliable at room temperature."[208] At issue was:

> [w]hether the tungsten of which the patent speaks is the tungsten of nature with its inherent quality of ductility or is a new metal produced by [the inventor] Coolidge which is wholly different from anything that nature provides. If it is a natural thing then clearly, even if Coolidge was the first to uncover it and bring it into view, he cannot have a patent for it *because a patent cannot be awarded for a discovery or for a product of nature*, or for a chemical element.[209]

Gen. Elec. has been cited frequently as a product of nature decision,[210] but it was wrongly decided on scientific grounds. One known approach to making tungsten was the "amalgan process," referred to in *Gen. Elec.* from U.S. Patent No. 1,018,502 but the resulting filament remained "fragile and therefore not so serviceable as a wire drawn from ductile tungsten."[211] Coolidge, as the basis for the his patent, followed the generally known processes of using a metal powder and binding agent, which was subsequently removed chemically or thermally, and he continued to treat and work the brittle tungsten at a high temperature, imparting the ductility which made

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[203] *Id.* at 133.

[204] Gen. Elec. Co. v. De Forest Radio Co., 28 F.2d 641, 641 (3d Cir. 1928); *see also* U.S. Patent No. 1,082,933 (filed June 19, 1912).

[205] *Gen. Elec.*, 28 F.2d at 641.

[206] *Id.* at 642–43.

[207] *Id.* at 644.

[208] *Id.* at 641–42.

[209] *Id.* at 642 (emphasis added). Author notes that, on the point of the issuance of a patent for an element, the judge was in error, but the first of the man-made elements was still a decade off.

[210] *See* Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 162 (4th Cir. 1958).

[211] *Gen. Elec.*, 28 F.2d at 643; *see also* U.S. Patent No. 1,018,502 (filed July 6, 1905).

drawing possible.[212] Subsequently, it was recognized that the brittle forms of tungsten which preceded Coolidge's form was indeed "pure tungsten as far as analysis could show."[213] For making ductile tungsten the problem then was not one of purifying the metal, rather the problem was caused by the grain structure of the tungsten itself "[b]y using a sufficiently high temperature initially, it was found that as the metal was subjected to mechanical work its ductility increased."[214] In simple terms, ductile tungsten is a man-made product, distinct from naturally occurring tungsten, even in purified form.[215] Hence, it may be interpreted from Judge Woolley's ruling that ductile tungsten is a product of nature, which indicates a technical misunderstanding of the structure of natural tungsten in purified form, which has a low degree of ductility.

The case was appealed on the grounds that "the court misunderstood and therefore misstated certain chemical characteristics of the invention . . . ."[216] However, Judge Woolley ruled that "[i]t may be that in the complexity of the subject matter of the invention certain of our statements were not, from a scientific standpoint, precisely accurate,"[217] yet denied the petition for a rehearing. As a consequence, an important product of nature precedent was established which failed to consider all the ways that human intervention can be involved in creating a product distinct from its natural origins. In this regard there is some conflict with the Supreme Court's decision in *Funk Bros.*, where it is stated that "the qualities of metals, are part of the storehouse of all men" without being specific as to which "qualities" were referenced.[218]

4. Ductile Vanadium, Thorium, and Uranium, from In re Marden

All three elements—ductile vanadium, thorium, and uranium—are naturally occurring, although reduction to a pure state can be complex. All arguments to construe these three elements as ductile products were rejected under *General Electric* on the basis that the elements are products of nature with well-established malleability properties.[219] Unlike tungsten, however, the natural state of these three elements is indeed ductile.[220]

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[212] *Gen. Elec.*, 28 F.2d at 644.

[213] *Id.* at 643–644.

[214] *See* Properties of Tungsten, *MIDWEST TUNGSTEN SERV.*, http://www.tungsten.com/tunghist.html (last visited Jan. 30, 2012).

[215] *Gen. Elec.*, 28 F.2d at 646–47.

[216] *Id.* at 650.

[217] *Id.*

[218] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

[219] *In re* Marden, 47 F.2d 958, 959 (C.C.P.A. 1931); *In re* Marden, 48 F.2d 428, 429 (C.C.P.A. 1931); *In re* Marden, 47 F.2d 957, 958 (C.C.P.A. 1931).

[220] N. N. GREENWOOD & A. EARNSHAW, CHEMISTRY OF THE ELEMENTS 978–79 (Butterworth-Heinemann, 2d ed. 1997) (describing the physical properties of Vanadium in its natural state). *Id.* at 1004 (describing Tungsten as naturally occurring in a powdered form); *Id.* at 1232 (describing the soft properties of the Lanthenide elements, Thorium and Uranium).

5. Materials Isolated from Nature: Ex parte Latimer

In *Ex Parte Latimer*,[221] the patentee, Latimer, had developed a process for separating the long fibers of *Pinus australis* from the pulpy and resinous parts of the pine needle so that they could be adapted for spinning and weaving. The process patent was granted, but the product application was rejected as being indistinguishable from other vegetable fibers.[222] "The different fibers differ in characteristics as to length, strength, and fineness . . . . [T]hese differences are not at all due to the process by which they are removed from the matrices in which they have grown, but to the process of nature in developing and growing them."[223] "[T]he mere ascertaining of the character or quality of trees that grow in the forest and the construction of the woody fiber and tissue of which they are composed is not a patentable invention."[224] "[S]o in the present case the fiber not only is old, . . . but it is a natural product and can no more be the subject of a patent in its natural state when freed from its surroundings than wheat which has been cut by a reaper . . . or by some new method of reaping can be patented as wheat cut by such a process."[225]

6. Materials Isolated from Nature: Ex parte Berkman & Berkman

Inventors Berkman and Berkman sought both process and product protection for pigments extracted from plant materials like leaves.[226] The process claims were accepted but the product claims rejected. The USPTO examiners identified claims 35, 40, and 43 as representative of the product claims.[227] Claim 35 discloses plant extracts "in substantially unaltered form" as a product by process.[228] Claim 40, as interpreted by the examiners, is likewise a product by process claim, which involves "a more complete recital of the process,"[229] than claim 43 which is for "active material derived from plants."[230] While the resultant products were described as "practically identical with such units occurring in the living plant structure," once removed from a living environment they had exhibited a tendency to instability "against the actions of light and oxidation".[231] Indeed, that enhanced stability, which is identified as the distinguishing characteristic of the invention, is a trait made possible by being "substantially free of cellulosic material, electrolytes, and enzymes;" meaning purified.[232]

The examiners cited a product of nature bar.[233] "[C]laims to a product formed by nature's processes are, as a rule, held to be invalid."[234] "An exception is not made

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[221] *Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123.
[222] *Id.* at 123.
[223] *Id.* at 125.
[224] *Id.*
[225] *Id.* at 127.
[226] *Ex parte* Berkman & Berkman, 90 U.S.P.Q. (BNA) 398, 399 (B.P.A.I. 1951).
[227] *Id.*
[228] *Id.*
[229] *Id.* at 401.
[230] *Id.*
[231] *Id.* at 399.
[232] *Id.* 399–400.
[233] *Id.* at 400.

when the product so obtained has enhanced properties, such as stability, or purity."[235] Additionally, specific rationales for rejecting the claims-in-suit were offered as well.[236] Considering the "representative" claims 35, 40 and 43, claim 35 did not "recite all of the essential steps of the process." Claim 40, while providing a more complete description of the process, actually defined a "theoretical concept"—the claimed product-by-process being identical to the natural one.[237] Finally, claim 43 is an "extremely broad" product claim of plant material in a purified form.[238]

7. Synthetic Versions of Natural Products

In re Merz[239] involved product claims to a purified version of a synthetic form of a natural product.[240] Claim 22 is representative of synthetic versions of natural products artificial ultramarine containing non-floatable impurities having improved brightness of shade. The USPTO examiner found that "regardless of the superior properties of the product over that previously produced . . . they are not such as to take the case out of the general rule . . . that a product which has been purified is not patentable over the unpurified product."[241]

"Artificial ultramarine is a well-known synthetic reproduction of the ultramarine of nature. The product has been created by both nature and man."[242] The "[a]pplicant has taken an old product, either naturally or synthetically produced, and removed the impurities therefrom."[243]

In the case *In re King*,[244] a similar issue arose regarding product and process claims for vitamin C.[245] The compound at issue had been previously discovered by Szent-Gyorgyi, but not recognized (i.e., not disclosed) as vitamin C with antiscorbutic properties. "All they did [] was [] produce a compound that was old in the art . . . ."[246] "The substance of [Szent-Gyorgyi's discovery] could be employed in medicine exactly in the same fashion and with the same results as the product of the appealed claims, [t]herefore, there was no invention in the discovery that vitamin C is hexuronic acid."[247]

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[234] *Id.* at 401.
[235] *Id.*
[236] *Id.*
[237] *Id.*
[238] *Id.*
[239] *In re* Merz, 97 F.2d 599 (C.C.P.A. 1938).
[240] *Id.* at 599.
[241] *Id.* at 600.
[242] *Id.*
[243] *Id.*
[244] *In re* King, 107 F.2d 618, 618 (C.C.P.A 1939).
[245] *Id.* at 618.
[246] *Id.* at 619.
[247] *Id.*

B. Patentable Products Derived From Nature

1. Cultivated Plant Life and Sports and Mutants

The Plant Patent Act is justified for cultivated plants which "resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man . . . ."[248] A sport is a variation at the bud level and a mutant one at the seed level; variations may be either naturally occurring or induced such as through radiation.[249] The use of the term "unique" lacks some horticultural specificity because wild plants are frequently quite heterogeneous meaning their characteristics vary notably from specimen to specimen.[250] The interpretation conveyed is quite clear—newly created varieties of cultivated plants are interpreted to be unique, and in truth, at the genetic level, they likely are.[251] However, the uniqueness may not be discernable in a meaningful aspect.

For sexually propagated plants, the initial rejection was based on the examiners interpretation that Congress, in passing the plant-specific Plant Variety Protection Act of 1970 and the Plant Patent Act, had intended those to be the exclusive forms of protection allowed.[252] The Board of Patent Appeals and Interferences disagreed that the scope of patentable subject matter under section 101 had been so restricted[253]

2. Human-made Microorganisms

The well-known *Chakrabarty* case subsequently led to the identification of both higher plants and animals as patentable subject matter.[254] Ultimately, the patentability of microorganisms was mandated under the patent harmonization requirements in article 27 of the Trade-Related Aspects of Intellectual Property Rights ("TRIPS").[255] In contrast to its decision in *Funk Bros.,* the Supreme Court concluded that "the patentee [in *Chakrabarty*] has produced a new bacterium with markedly different characteristics from any found in nature . . . . His discovery is not

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[248] S. REP. NO. 71-315, at 6 (1930).

[249] *Id.* at 3, 7.

[250] *See* INT'L UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS, GENERAL INTRODUCTION TO THE EXAMINATION OF DISTINCTNESS, UNIFORMITY AND STABILITY AND THE DEVELOPMENT OF HARMONIZED DESCRIPTIONS OF NEW VARIETIES OF PLANTS 19–22 (Apr. 19, 2002), *available at* http://www.upov.int/en/publications/tg-rom/tg001/tg_1_3.pdf. (providing as an example that, the International Union for the Protection of New Varieties of Plants, non-trivial guidelines for determining when a variety is indeed homogenous; presumably identifying overall uniqueness would be that much more complex).

[251] *Id.* at 15, 19.

[252] 7 U.S.C. § 2321 (1970).

[253] *Ex Parte* Hibberd, 227 U.S.P.Q. (BNA) 443, 444 (B.P.A.I. 1985).

[254] Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980).

[255] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125, 1869 U.N.T.S. 299, art 27, *available at* http://www.wto.org/english/docs_e/legal_e/27-TRIPS.pdf.

nature's handiwork, but his own . . . ."[256] In addition to inoculum and process claims, the patent claims a "bacterium" created by "genetic transfer."[257]

As if to distinguish this invention from the unspecified mixture of inoculants which were characterized *Funk Bros.*,[258] the description notes that:

> Pseudomonas and other bacteria species are known to degrade the aliphatic, aromatic and polynuclear aromatic hydrocarbon compounds, but, unfortunately any given strain can degrade only a particular component. For this reason, prior to the instant invention, biological control of oil spills had involved the use of a mixture of bacterial strains, each capable of degrading a single component of the oil complex on the theory that the cumulative degradative actions would consume the oil and convert it to cell mass. This cell mass in turn serves as food for aquatic life. However, since bacterial strains differ from one another in: (a) their rates of growth on the various hydrocarbon components, (b) nutritional requirements, production of antibiotics or other toxic material, and (c) requisite pH, temperature and mineral salts, the use of a mixed culture leads to the ultimate survival of but a portion of the initial collection of bacterial strains. As a result, when a mixed culture of hydrocarbon-degrading bacteria are deposited on an oil spill the bulk of the oil often remains unattacked for a long period of time (weeks) and is free to spread or sink.[259]

The decision does note that section 101 has limits, making particular reference to prior judicially created bars to patentable subject matter to include the laws of nature, physical phenomena, and abstract ideas.[260] *Chakrabarty* was affirmed in 2001 by *J.E.M. Ag Supply*[261] with regards to the patentability of agricultural plants.[262] There, the specific issue was whether other forms of protection specifically for plants pre-empted the application of utility patents. The decision was to the negative.[263]

3. Man-made Animals from Ex parte Allen

The Board of Patent Appeals and Interferences treated *Ex parte Allen*[264] as a direct extension of *Chakrabarty*.[265] In its opinion in *Allen*, the Court noted that:

> the Supreme Court made it clear in its decision in *Chakrabarty* . . . that [s]ection 101 includes man-made forms. The issue, in [the Court's] view, in

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[256] *Chakrabarty*, 447 U.S. at 310.
[257] U.S. Patent No. 4,259,444 (filed June 7, 1972).
[258] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 129 (1948).
[259] U.S. Patent No. 4,259,444, col 5, l. 15 (filed June 7, 1972)..
[260] *Chakrabarty*, 447 U.S. at 309.
[261] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 129–30 (2001).
[262] *Id.* at 129–30.
[263] *Id.* at 132.
[264] *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425 (B.P.A.I. 1987).
[265] *Id.* at 1426–27.

> determining whether the claimed subject matter is patentable under [s]ection 101 is simply whether that subject matter is made by man. If the claimed subject matter occurs naturally, it is not patentable subject matter under [s]ection 101.[266]

The Court continued to explain, by way of example, that "[t]he examiner has presented no evidence that the claimed polyploidy oysters occur naturally without the intervention of man, nor has the examiner urged that polyploidy oysters occur naturally."[267] This leads to the conclusion that the "claimed polyploidy oysters are non-naturally occurring manufactures or compositions of matter within the confines of patentable subject matter under [section] 101.[268] In the case of the *Allen* appeal however the product was judged to be obvious under the known art leading to the rejection of the application.

4. Man-made Elements

Although the Periodic Table of Elements predicts the existence of potentially hundreds of elements, only ninety-two are naturally occurring with the remainder being synthetic.[269] All of the man-made elements are radioactive and some of the higher weight elements can be made to exist for mere hundredths of a second.[270] An exception is Americium, element ninety-five, and its two known isotopes, Am-241 and Am-242.[271] Americium was invented in 1944. A patent was applied for in 1946 and granted in 1964.[272] U.S. Patent No. 3,156,523 in its first three claims discloses: (1) element ninety-five, (2) Am-241, and (3) Am-242.[273] The application was subject to an appeal, but the grounds were anticipation based on a method of manufacture, not on product-of-nature grounds.[274] The grant was based on the newness of this element and its obvious human involvement in relying on a complex nuclear reactor.[275] With a maximum isotope half-life of less than 7500 years, any Americium naturally created during the radioactive primordial stage of the earth's development would have long disappeared so that any extant Americium can be reasonably concluded to be man-made.[276]

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[266] *Id.*
[267] *Id.* at 1427.
[268] *Id.*
[269] *See* GREENWOOD, *supra* note 220.
[270] *Id.*
[271] U.S. Patent No. 3,156,523 (filed Aug. 23, 1946).
[272] *Id.*
[273] *Id.*
[274] *In re* Seaborg, 328 F.2d 996, 997 (C.C.P.A. 1964).
[275] *Id.* at 999.
[276] *It's Elemental - The Element Americium*, JEFFERSON LAB, http://education.jlab.org/itselemental/ele095.html (last visited Jan. 30, 2012).

5. Purified Compounds of Known Products with Differences in Kind not Degree

a. Acetyl Salicylic Acid (Aspirin)

The properties and existence of aspirin (initially a Bayer trade name for salicylic acid) were first reported about 400 B.C. by Hippocrates who used parts of the willow tree to treat headaches, pain, and fever.[277] It was not until 1829 before it was recognized that the compound called salicin was the active ingredient, but salicylic acid proved to be injurious to the stomach, severely limiting its usefulness.[278] The first pure, and hence usable, form of the acid was discovered by Hoffman in 1898 and patented in the U.S. in 1900.[279] The patent was infringed, and as a defense, the claim was made that the Hoffman process for purification was obvious under the prior art, particularly that used by Kraut.[280] Hoffman showed that the Kraut process led to an impure form, "having a small percentage of free salicylic acid, and some other impurities."[281] "It follows from these details that the two compounds [Kraut's and Hoffman's] are absolutely different."[282] The Kraut-produced compound was found to be "comparatively useless" while the Hoffman product was "immediately successful to an extraordinary degree."[283] "[Hoffman] took a comparatively worthless substance and changed it into a valuable one. It was he, and not Kraut or the other famous chemists of the prior art, who gave to the world this valuable remedy."[284]

b. Adrenaline

Adrenaline is the trade name given to the product of the suprarenal glands, first identified in 1894, and subsequently recognized as the first hormone to be analyzed and used as a therapeutic.[285] But it was not until 1901 that a chemist, Takamine, was able to purify the active principal.[286] Takamine filed for a patent on the principal in 1900, subsequently divided it into two divisionals in 1903.[287] Claim 1 of the '176 patent is for "a substance possessing the herein described physiological characteristics and reactions of the suprarenal glands in a stable and concentrated form, and practically free from inert and associated gland-tissue", which is to say a

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[277] Matthew E. Falagas et al., *Science in Greece: From the Age of Hippocrates to the Age of the Genome,* 20 J. FED. AM. SOC'Y EXPERIMENTAL BIOLOGY 1946, 1947–48 (2006).

[278] R.L. Mueller & S. Scheidt, *History of Drugs for Thrombotic Disease. Discovery, Development, and Directions*, 89 CIRCULATION 432, 436 (1994).

[279] U.S. Patent No. 644,077 (filed Aug. 1, 1898).

[280] Farbenfabriken of Elberfeld Co.v. Kuehmsted, 171 F. 887, 889–90 (N.D. Ill 1909).

[281] *Id.* at 888.

[282] *Id.*

[283] *Id.*

[284] *Id.* at 890.

[285] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 106 (1911).

[286] *Id.* at 114; see M.R. Bennett, *One Hundred Years of Adrenaline: The Discovery of Autoreceptors*, 9 CLINICAL AUTONOMIC RES. 145, 145 (1999).

[287] *See Parke-Davis*, 189 F. at 114; *see also* U.S. Patent No. 730,176 (filed Nov. 5, 1900); U.S. Patent No. 753,117 (filed May 12, 1903).

product patent.[288] These patents were licensed to Parke-Davis who then sued when they were infringed.[289] The decision by Judge Hand, a finding of infringement of most claims of the two patents, is one of the underlying products-of-nature decisions.[290] Dutfield credits this decision, certainly a complex one, as "open[ing] the door for other kinds of natural products decades later."[291]

Prior to Takamine's invention, the standard medical practice was to dry and powder the suprarenal glands and sell in a liquid form preserved with chloretone.[292] On occasion this mixture was used intravenously but being a mixture of many organic substances it was recognized as "an extremely dangerous substance for injection into the body."[293] Takamine's purified compound removed much potential for injury, leading Judge Hand to declare, "[t]hat [purification] was a distinction not in degree, but in kind."[294] "[Purifying it] became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent."[295] The mention of the commercial dimension was not inconsequential because "as soon as Takamine Adrenaline became known, the use of the dry gland solution . . . practically disappeared altogether.[296] As in *Farbenfabriken v. Kuehmsted*,[297] the response of the market was given significant weight in determining whether the product was indeed an invention.[298]

Judge Hand's judgment, however, did not end there. He noted that "even if [purified adrenaline] were merely an extracted product without change, there is no rule that such products are not patentable."[299] Additionally, he pointed out that "[t]he line between different substances and degrees of the same substance [e.g., level of purity] is to be drawn from the common usages of men rather than from nice considerations of dialectic."[300] Clearly, the market considered Takamine Adrenaline to be a different substance.[301] However, the *Parke-Davis* case addressed the issue of novelty under section 102 and not the issue of patentable subject matter under section 101,[302] which was the question in *Myriad*.[303] Thus, Judge Hand's oft-quoted statement should be considered merely dicta.[304]

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[288] U.S. Patent No. 730,176.

[289] *Parke-Davis*, 189 F. at 95.

[290] *Id.* at 114.

[291] Graham Dutfield, *Who Invents Life: Intelligent Designers, Blind Watchmakers, or Genetic Engineers?* 5 J. INTELL. L. PRAC. 531, 531 (2010).

[292] *Parke-Davis*, 189 F. at 96.

[293] *Id.*

[294] *Id.* at 103.

[295] *Id.* at 106. However, it should be recognized that at the time of Takamine's discovery, it was not known that adrenaline was indeed a chemical compound subject to isolating from the gland, or if it "might altogether disappear upon their disassociation." *Id.*

[296] *Id.*

[297] Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 F. 887, 887 (N.D. Ill. 1909).

[298] *Parke-Davis*, 189 F. at 110.

[299] *Id.* at 103.

[300] *Id.*

[301] *See id.* at 115 (noting that "as soon as Takamine put out his discovery, other uses practically disappeared.").

[302] 35 U.S.C. §§ 101–102 (2006).

[303] Myriad, 702 F. Supp. 2d 181, 218 (S.D.N.Y. 2010).

[304] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: 2010-11 SUPPLEMENT 36 (LexisNexis, 4th ed. 2010).

c. Vitamin B_{12}

The initial product claims for what was subsequently named vitamin B_{12} were rejected by the District Court for the Western District of Virginia on the bases of being a product of nature and lack of invention, the process claims having been withdrawn.[305]

The search for vitamin B_{12} had its origin in treatments for pernicious anemia when, in 1926, it was recognized that sufferers of the disease benefited from the addition of substantial amounts of cattle liver.[306] While somewhat effective, this method of treatment was limited by the substantial cost and the inability of some patients to physically tolerate it.[307] The scientific community was, however, ignorant of the active component of the livers, leading to a multi-faceted, nearly thirty-year research undertaking leading to the discovery of B_{12}.[308] The discovery process has a bearing on the patent dispute, so a brief overview is required to comprehend the issues involved.[309]

The initial exploration, understandably, focused on the identification of the unknown component of liver, which, among other things, stimulated the growth of rats.[310] A leading researcher in this endeavor, Dr. Shorb, then at the University of Maryland, was put under contract with Merck to continue the work, with any resulting patent rights to be assigned to Merck.[311] At roughly the same time, a shortage of a poultry feed supplement led to an exploration for alternatives which would stimulate growth and enhance feed utilization.[312] "It does not appear, however, that anyone related the anti-pernicious anemia principle to the growth stimulating 'animal protein factor,' nor had anyone experimenting with the 'animal protein factor' isolated, identified, or determined the nature of the unknown substance that produced the observed effect."[313]

In 1947 Merck resumed work on the isolation of the anti-pernicious anemia factor in liver, in that instance exploring fermentation materials as a possible source.[314] By the end of the year a pure, crystalline material was obtained.[315] Other Merck researchers, continuing work on liver, themselves isolated a pure, crystalline material which proved to be the long-elusive "anti-pernicious anemia factor" and identical to that previously isolated from the fermentation materials. This material was subsequently named vitamin B_{12}.[316]

The District Court's initial rejection of the product claims were in-part based on "lack of invention" based principally on the work of Dr. Shorb.[317] However, the claims related to B_{12} derived from fermentation materials with no claim to a liver

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[305] Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 157 (1958).
[306] *Id.* at 158.
[307] *Id.*
[308] *Id.* at 159.
[309] *See id.* at 160–61.
[310] *Id.* at 159.
[311] *Id.*
[312] *Id.*
[313] *Id.*
[314] *Id.*
[315] *Id.* at 160.
[316] *Id.*
[317] *Id.* at 157.

derivation of any activity level.[318] "[B]ut there is nothing to suggest that [Dr. Shorb] ever envisioned anything in the nature of the compositions developed by the patentees, or, indeed, that she [or anyone else] ever supposed that anti-pernicious anemia activity might be found in any material other than liver."[319]

The real issue then, and the one of relevance here, is that the claim was to a product of nature and hence invalid.[320] The Federal Circuit held that "[t]o the extent that the 'product of nature' defense has validity, as urged here, it is a contention that the patented compositions are not 'new and useful compositions of matter' within the meaning of [section] 101 of the [Patent] Act."[321] The court considered the facts and found that they are far from the premise of that principle. It noted that "[u]ntil the patentees produced them, there were no such B_{12} active compositions." No one had produced even a comparable product. The active substance remained unidentified and unknown. The new product, not just the method, had such advantageous characteristics as to replace the liver products.[322]

The decision though has ramifications beyond this case:

> [t]here is nothing in the language of the Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability. All of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials. The 'matter' of which patentable new and useful compositions are composed necessarily includes naturally existing elements and materials.[323]

C. Discussion

1. All Subject Matter

Before considering the particulars of gene patents as they apply to the "product of nature" issue it is appropriate to consider the issue for all subject areas. The courts, when deciding on the issue of products of nature, tend to do so in broad terms.[324] Statements in *In re Merz* are notably sweeping.[325] The superior properties of the purified product "are not such as to take the case out of the general rule as set forth in the following case; that a product which has been purified is not patentable over the unpurified product."[326] On this point the USPTO in concurrence explained that the Board"s decision "does not affect the principle and practice that products

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[318] *Id.* at 160.
[319] *Id.*
[320] *Id.* at 161.
[321] *Id.* at 162.
[322] *Id.* at 162–63.
[323] *Id.* at 161–62.
[324] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).
[325] *In re* Merz, 97 F.2d 599, 601 (1938).
[326] *Id.* at 600.

found in nature will not be considered to be patentable subject matter under [sections] 101 and/or 102. . . . [A] composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties, or combination not present in the original article . . . .[327]

The Supreme Court also rendered sweeping judgments on the issue of purification noting that "[w]hether a slight difference in the degree of purity of an article produced by several processes justified denominating the product's different manufacturers . . . may well be doubted . . . ."[328] Yet a number of decisions allowing the patenting of materials found in or from nature are no less emphatic. Those decisions relate generally to "purification" as opposed to man-made products as in *Chakrabarty* and Americium.[329] When the courts did reject a patent for a product like tungsten for which the purification was indeed one of kind and not degree, the reasonable conclusion is one of a technical judicial error.

Even the *Funk Brothers* decision, while frequently referred to as a key product of nature decision, is on closer reading less than clear. This is pointed out by Justice Frankfurter in his concurring opinion where he observed, that "[i]t only confuses the issue, however, to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation."[330] Justice Frankfurter continues by explaining that the invention in *Funk Brothers* is not negated by the fact that the composite had no properties distinct from those of the individual components.[331] The mixture indeed has the "new property of multi-service applicability."[332] For him, the issue was insufficient disclosure because the exact strains to be used in the mix were not disclosed and indeed were not identifiable other than by not being mutually incompatible, which is the basis of the invention.[333] As claimed, the patent then applies to *all* possible mixtures of compatible strains, so that the product of nature issue is not pivotal, at least for Frankfurter.[334] "The Court does not mean unwittingly to pass on the patentability of such products by formulating criteria by which future issues of patentability may be prejudged."[335] Yet as the *Myriad* case indicates, that is exactly what has occurred.

Of course it is but a small step from the imprecision of the concept of 'product of nature' to that of the law or principal of nature. Again from *Pitner*:

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[327] PATENT AND TRADEMARK OFFICE, NOTICE: ANIMALS-PATENTABILITY, 1077 OFFICIAL GAZETTE U.S. PAT. & TRADEMARK OFF. 8 (Apr. 21, 1987) (specific application is to higher animals but the policy is general as to application).

[328] American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566, 594 (1874).

[329] *See, e.g.*, Farbenfabriken of Elberfeld Co v. Kuehmsted, 171 F. 887, 890 (N.D. Ill. 1909) ("[Hoffman] took a comparatively worthless substance and changed it into a valuable one [aspirin]."); Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (1911) ("[Purified adrenaline] became for every practical purpose a new thing commercially and therapeutically. . . . That [purification] was a distinction not in degree, but in kind.").

[330] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 134–35 (1948).

[331] *Id.* at 135.

[332] *Id.*

[333] *Id.* at 133.

[334] *Id.* at 134–35. Justice Frankfurter states that "[u]nless I misconceive the record, Bond makes no claim the Funk Brothers used the same combination of strains that he had found mutually compatible." *Id.* at 133.

[335] *Id.* at 135.

> [s]eldom is there any discovery of a new phenomenon of an old chemical product that does not call for the old product's contact with a material to which it must be applied by human agencies before the phenomenon occurs. In all such cases the discoverer is well outside of the rule which excludes the issuance of patents to those who have merely discovered a law or principle of nature or fundamental truth.[336]

> A discovery in the field of science of a new quality or phenomenon of an old product may be (other necessary facts such as being first, timely application, etc., existing) the proper subject of a patent. It does not fall within the term 'law of nature' as that expression is used in patent law.[337]

The Court in *Pitner* also comments on the inconsistency of prohibiting patents for products of nature based solely on the source of materials:

> It is true that an old substance with newly discovered qualities possessed those qualities before the discovery was made. But it is a refinement of distinction both illogical and unjustifiable and destructive of the laudable object of the statute to award a patent to one who puts old ingredient A with old ingredient B and produces a cure for ailment C, and deny patent protection to one who discovers that a simple and unadulterated or unmodified root or herb or a chemical has ingredients or health-giving qualities, hitherto unknown and unforeseen.[338]

Similarly, the court in *Merck* notes that "[a]ll of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials."[339]

From this overview of leading cases generally associated with products of nature there is much evidence that inventions involving notable human involvement—identified in this instance as the development of products not previously known—are patent eligible.[340] This group includes man-made microorganisms,[341] plants,[342] animals,[343] some periodic elements,[344] and vitamin B_{12}.[345] These products, however, do not raise complex patentability issues because there is substantial evidence of human ingenuity. Of course, mere effort does not replace novelty as in the cases of ductile Vananium (Columbium), Thorium, and Uranium, which are ductile in their

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[336] Dennis v. Pitner, 106 F.2d 142, 145 (1939).

[337] *Id.* at 146.

[338] *Id.* at 145.

[339] Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 161–62 (1958).

[340] *See* Linda J. Demaine & Aaron X. Fellmeth, *Natural Substances and Patentable Inventions,* 300 SCI. 1375, 1375 (2003).

[341] Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).

[342] S. REP. No. 71-315 at 1 (1930); *Ex Parte* Hibberd, 227 U.S.P.Q. (BNA) 443, 444–45 (B.P.A.I. 1985).

[343] *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426 (B.P.A.I. 1987).

[344] *See In re* Marden, 47 F.2d 958, 958 (C.C.P.A. 1931); *In re* Marden, 48 F.2d 428, 428 (C.C.P.A. 1931); *In re* Marden, 47 F.2d 957, 957 (C.C.P.A. 1931).

[345] *See* Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 157, 164 (1958).

natural (pure) state even if achieving that state can be complex.[346] Simplified, these are novelty cases rather than product of nature cases.

In cases where the product in its pure form differs in 'kind, not degree,' there is greater difficulty in making the distinction. In this situation, reference is made to aspirin[347] and adrenaline.[348] In those instances, the novelty requirement was strongly enhanced by the utility exhibited through market success.[349] In *Farbenfabriken v. Kuehmsted*,[350] the predecessor compound was found to be "comparatively useless" while the patented product was "immediately successful to an extraordinary degree."[351] "[The inventor] took a comparatively worthless substance and changed it into a valuable one."[352] *Raytheon v. Roper*[353] emphasized the inter-connectedness of novelty and utility by noting that "[p]roof of such utility is further supported when . . . the inventions set forth . . . have on their merits been met with commercial success."[354]

As the preceding paragraphs indicate, the product of nature patentability issue need not have been raised in these cases. They were addressed effectively by standard non-obviousness, novelty, and utility considerations. Nor is it clear that a product of nature consideration was required for those cases previously discussed where product patents were denied on appeal. That is, while the product of nature factor was raised there were other, factors apart from section 101 which would have precluded patentability. For example, in *Ex parte Berkman & Berkman*,[355] in addition to the product of nature rejection, the USPTO Board of Appeals (the "Board") also identified the "extremely broad" and "theoretical" aspect of claims as a basis for rejection.[356] Alternatively, the series of *In re Marden* cases deal with the novelty requirement.[357] *In re King* and *In re Merz* are also novelty cases where the court held that a synthetic version of a known natural product is not novel.[358] Additionally, while the focus of *Ex parte Latimer* has been on the "natural products" dimension, the USPTO examiner noted that "[i]f the applicant's process had another final step by which the fiber thus withdrawn or separated from the leaf or needle in its natural state where changed . . . then, passing through the exigencies of such a process would be treated and become something new or different from what it is in its natural state."[359] In other words, *Latimer* is yet another novelty case.

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[346] *In re* Marden, 47 F.2d at 958; *see also Ex parte* Berkman & Berkman, 90 U.S.P.Q. (BNA) 398, 399 (B.P.A.I. 1950).

[347] *See* Farbenfabriken of Elberfeld Co v. Kuehmsted, 171 F. 887, 887 (N.D. Ill. 1909).

[348] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 97 (S.D.N.Y 1911).

[349] *Id.* at 115; *Kuehmsted*, 171 F. at 890.

[350] *Kuehmsted*, 171 F. at 887.

[351] *Id.* at 890.

[352] *Id.*

[353] Raytheon v. Roper, 724 F.2d 951 (Fed. Cir. 1983).

[354] *Id.* at 959.

[355] *Ex parte* Berkman & Berkman, 90 U.S.P.Q. (BNA) 398 (B.P.A.I. 1950).

[356] *Id.* at 401.

[357] *See In re* Marden, 47 F.2d 958 (C.C.P.A. 1931); *In re* Marden, 48 F.2d 428 (C.C.P.A. 1931); *In re* Marden, 47 F.2d 957 (C.C.P.A. 1931).

[358] *In re* King, 107 F.2d 618, 620 (C.C.P.A 1939); *In re* Merz 97 F.2d 599, 601 (C.C.P.A. 1938).

[359] *Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123, 127.

Even as noted above, *Funk Bros.* could have been decided on grounds other than product of nature.[360] Justice Frankfurter in his concurrence did recognize an invention, but with a lack of enablement.[361] Similarly, scholar Donald Chisum states that *Funk Bros.* is not a statutory class of subject matter case but can "perhaps best [be] viewed as an interpretation of the non-obviousness or 'invention' requirement."[362] Other related cases, such as *Cochrane v. Badische Anilin & Soda Fabrik*,[363] have been settled without resorting to the statutory subject matter argument. For example, in *Cochrane*, the product claims for alizarine, a natural pesticide, were denied.[364] "[T]he article produced by the process described was . . . an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time . . . . Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially for the first time . . . ."[365]

From this overview it should be apparent that product of nature cases can be resolved on statutory patentability grounds without adding the complexity of a non-statutory and poorly defined consideration like the judicially-imposed product of nature bar. Scholars Conley and Makowski note that "[t]he lower courts have been less than helpful in delineating the boundary between products of nature and patentable inventions. [This is evidenced by the fact that] courts have been inconsistent in deciding whether the products of nature problem is a section 101 subject matter issue, a section 102 novelty issue, a section 103 non-obviousness issue, or some combination of the three."[366]

Therefore, the relevant question is not if the degree of purity is a section 101 issue, but if the invention satisfies sections 102, 103, and the first paragraph of section 112.

2. Applications to Genes

Accepting, that cDNA is indeed man-made,[367] while setting aside a consideration of the method claims,[368] the remaining *Myriad* claims under consideration as true products of nature are but four: claims 1 and 5 from the '280 patent and claims 1 and 6 from the '492 patent. What about the patentability of the Myriad BRCA1 and BRCA2 genes in their physical form? Are they patentable subject matter or not as physical entities in the absence of the product of nature ban? The focus here is not

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[360] *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 135 (1948).

[361] *See id.*

[362] 1 DONALD S. CHISUM , CHISUM ON PATENTS 1.02[7][b] (2007).

[363] Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884).

[364] *Id.* at 311–12.

[365] *Id.*; *see generally* John H. Schrader, *Patentability of Natural Products, Plant Isolates, and Microbiological Products, in* PATENTS FOR CHEMICAL INVENTIONS 99–106 (Am. Chem. Soc'y, 1964) ("The key question involved in the situation of this type appears to be one of utility.").

[366] John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II)*, 85 J. PAT. TRADEMARK OFF. SOC'Y, 371, 379 (2003).

[367] *See* Amicus Brief for the United States, *supra* note 13, at 14–15.

[368] Myriad Appeal, 653 F.3d 1329, 1334 (Fed. Cir. 2011).

an absolute answer of patentability of the physical component; that is an issue for experienced examiners and the courts. The goal is rather a more modest one of identifying if the section 102, 103, and first paragraph of section 112 statutory requirements beyond section 101 have been addressed even to a peripheral degree.

The two BRCA genes in *Myriad* demonstrate utility.[369] Similarly, there is novelty; identifying the inheritability of cancer susceptibility down to the gene level.[370] The non-obviousness criteria is less clear as the "process and techniques used were well understood."[371] Nonetheless, locating the sequencing of the two genes took "considerable effort" and "ingenuity in overcoming technical obstacles."[372] Additionally, there is also Dr. Skolnick's insight of identifying and linking the Utah Mormon Genealogy with the Utah Cancer Registry to provide the large data set required for a statistical program for gene mapping.[373] While not definitive, there exists, at minimum, a basis for evaluating non-obviousness.[374] The adequacy of the specification remains a question at least in regards to claim 6 of the '492 patent which claims any human cancer susceptibility gene associated with mutated BRCA1 and BRCA2 genes.[375] In this instance the product is defined by its function raising questions about the satisfaction of the written description dimension of section 112.[376] Nevertheless, this is an issue for examination, not preemptory invalidation as a product of nature.[377]

Thus far this article has attempted to show that the patentability of the BRCA genes can be evaluated without resorting to the judicially-created product of nature bar. What is not considered in this overview is the so-called information dimension of genes, which has so many different interpretations.[378] For Judge Sweet, since the informational content of the isolated genes is identical to that of the native ones, there is no non-obviousness, while a majority of the Federal Circuit found that "information" is but a utility and a non-issue.[379] Judge Bryson in a partial dissent has particular misgivings, largely related to the scope of the four claims.[380] This article now turns to the intertwined issues of information, claim scope, and disclosure particularly as they apply to genes.

III. GENE PATENTS, INFORMATION, AND CLAIM SCOPE

Three aspects of the "information" dimension of genes are of relevance here. One is the abstract concept of ephemeral genes producing a molecule of unknown

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[369] Myriad, 702 F. Supp. 2d 181, 193 (S.D.N.Y. 2010); *see also* Amicus Brief of Boston Patent Law Ass'n in Support of Defendants-Appellants at 5–7, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 9-CV-4515) 2010 WL 4853325.

[370] *Myriad*, 702 F. Supp. 2d at 216; Amicus Brief for the United States, *supra* note 13, at 6–7.

[371] *Myriad*, 702 F. Supp. 2d at 202–03.

[372] *Id.* at 202.

[373] *Id.* at 201.

[374] *Id.* at 226.

[375] *Id.* at 212.

[376] *Id.* at 215.

[377] *Id.* at 229.

[378] Rogers, *supra* note 41, at 24.

[379] Myriad Appeal, 653 F.3d 1329, 1342 (Fed. Cir. 2011); *Myriad*, 702 F. Supp. 2d at 228–29.

[380] *Myriad Appeal*, 653 F.3d at 1373.

function.[381] This is Roger's third definition of a gene, or DNA sequence to apply his preferred terminology.[382] That definition is, "a DNA segment that reveals an 'image' of a DNA-derived molecule that is hypothesized to exist and function."[383] The second and quite distinct use is the treatment of genes in *Myriad* as a template for expressing proteins or functioning as genetic probes. And finally, there is the Federal Circuit decision which equated information with use.[384] Each is considered in turn.

A. Genes as Producers of Unspecified Proteins

If twenty percent of the human genome, to pick one important example, is presently patented then eighty percent is not, even though many of the eighty percent are sequenced with the data residing in large data banks.[385] One scholar describes the sources of the value of those data,[386] which suggests some form of intellectual property may be required as an incentive for private investments in genome mapping.[387]

Some form of intellectual property may indeed be required, possibly a copyright for a database, but that form will not be a patent due to a lack of specific utility.[388] In 2005, the Federal Circuit decided in the related case of a claimed invention involving five purified nucleic acid sequences, commonly referred to as "expressed tag sequences" ("ESTs"), for maize.[389] An EST is a short nucleotide sequence that represents a fragment of a complementary DNA ("cDNA") clone.[390] The EST may hybridize, or 'bond,' with a portion of DNA, indicating the presence of the complete gene corresponding to that EST.[391] In other words, they serve to monitor gene expression and to act as molecular markers.[392]

The patent examiner issued a final rejection because the claimed ESTs were "not supported by a specific and substantial utility."[393] Instead, the disclosed uses "were generally applicable to any EST."[394] When applied to monitor gene expression the

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[381] Rogers, *supra* note 41, at 26.

[382] *Id.* at 22.

[383] *Id.*

[384] Rogers, *supra* note 41, at 22.

[385] *Myriad Appeal*, 653 F.3d at 1355.

[386] Rogers, *supra* note 41, at 25–26.

[387] *See generally* J. CRAIG VENTER, A LIFE DECODED MY GENOME: MY LIFE, 234-36 (Penguin 2007) (discussing strategies for generating value from the private effort to map the human genome while making the sequence data publically available).

[388] 17 U.S.C. §§ 101, 103 (2006); Feist Pub'ns., Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 364–65 (1991) (noting that a compilation must have "more than a *de minimis* quantum of creativity" to be copyrightable); Jacqueline Lipton, *Balancing Private Rights and Public Policies:* Reconceptualizing *Property in Databases*, 18 BERKELEY TECH. L.J. 773, 784 (2003) (noting that an information product like a database is not patentable).

[389] *In re* Fisher, 421 F.3d 1365, 1367 (Fed. Cir. 2005).

[390] *Id.*

[391] *Id. See* KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT, 47–59 (BNA, 1995).

[392] *In re Fisher*, 421 F.3d at 1369.

[393] *Id.* at 1368.

[394] *Id.*

court concluded "the claimed ESTs in screens does not provide a specific benefit because the application fails to provide any teaching regarding how to use the data relating to gene expression."[395] The Federal Circuit concluded "because [the patentee] failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed" in its patent application the court will "have no choice but to conclude that the claimed ESTs do not have a 'substantial utility' under [section] 101."[396]

Extending this decision from an EST gene fragment to an entire gene, if the functionality of the gene is unknown, particularly if the function of the protein it encodes is unknown, the invention lacks specific and substantial utility.[397] Then the invention is not an invention under section 101, but then this is not a product of nature issue.

B. Genes as Formulae

Judge Sweet's use of the informational dimension of genes as it relates to products of nature is both less clear and more complex. In its essence, Judge Sweet appears to be arguing that attributes of the BRCA1 and BRCA2 genes are, and to function must be, identical to the native DNA, and it is from these attributes the genes derive their utility.[398] Here, reference is made specifically to the use of cDNA as a probe, among other uses.[399] Additionally, Judge Sweet argues that the treatment of genes as chemicals, as is established in *Amgen*,[400] is inappropriate because with chemicals the interest is in the formula for the chemical itself while with genes the attention is on the compound (typically a protein) produced by the gene.[401] The protein itself may or may not be novel, or otherwise unpatentable.

At one level, this interpretation is incorrect because cDNA is man-made, not a product of nature.[402] It is important to consider the product of nature issue in a broad context; if a gene must mimic nature to be useful, then is it functionally (if not necessarily physically) a product of nature?

Is in fact Judge Sweet's position on genes needing to mimic nature for much of their utility a product of nature consideration? What it actually is, is a restatement of the product of nature debate using slightly different terminology. Consider again adrenaline, one of the more influential of the product of nature cases in which adrenaline was purified (as compared to dried and powdered suprarenal glands) to provide a product "distinct . . . not in degree, but in kind."[403] The efficacy of the new product depended on mimicking adrenaline naturally produced by the body.

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[395] *Id.* at 1369.

[396] *Id.* at 1374.

[397] *Id.* at 1379.

[398] *See* Myriad, 702 F. Supp. 2d 181, 228–29 (S.D.N.Y. 2010).

[399] *Id.* at 106–97.

[400] Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1206 (Fed. Cir. 1991); *see Myriad*, 702 F. Supp. 2d at 185. *See e.g.*, GRUBB, *supra* note 41, at 211–29 (discussing the treatment of chemicals under patent law).

[401] *Myriad*, 702 F. Supp. 2d at 185.

[402] Myriad Appeal, 653 F.3d 1329, 1364 (Fed. Cir. 2011).

[403] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 106 (S.D.N.Y 1911); *see* Myriad, 702 F. Supp. 2d 181, 223 (S.D.N.Y. 2010).

Whether it was chemically identical is beside the point. Relevancy depends on functionality like the natural product. Thus, this aspect of Judge Sweet's decision, that the patented BRAC1 and BRCA2 genes had to function identically to the native BRCA1 and BRCA2 genes to be useful, adds nothing new to the product of nature discussion.[404] Finally, there is the Amicus Brief for the United States recognizing that "the mere fact that a non-naturally occurring polynucleotide . . . incorporates nucleotide sequences whose significance is derived from nature does not mean that the claim as a whole is directed to a product of nature."[405]

Judge Sweet's second position, that genes are a producer of compounds as well as being compounds in their own right, seems to propose that genes should in part be considered as a 'process' for providing specific proteins.[406] Indeed when transferred to an organism like *E. coli* that is exactly what genes are sometimes used for. That is, the multi-functionality of a gene can be described as it functioning simultaneously as a composition of matter and as a process for producing compounds, usually proteins.[407] In that case section 103(b) for "biotechnological processes" expressly provides for both composition and process claims in the same application, or separate applications under restrictive conditions.[408] While section 103(b) does not directly respond to Judge Sweet's concerns regarding genes differing from chemicals, it does indicate that the courts have observed and reconciled the relationship between compounds and processes.[409] In short, claiming a gene is an alternative approach to claiming its product, a protein, as Grubb has suggested.[410] This approach does not automatically raise the product of nature bar if either the starting material (the gene) or the product (the protein) is novel, going back to section 103(b).[411]

One aspect not raised by Judge Sweet regarding the chemical/gene relationship is the unpredictability of genes as producers of proteins, for multiple genes may produce the same protein or even a single coding region can be "read" in several ways leading to different outcomes. That situation can be contrasted with the common, if incorrect, perspective of the stability of chemical reactions. By contrast, in *In re Marzocchi & Horton*[412] the "well-known unpredictability of chemical reactions" was emphasized.[413]

The point being made here is that the correspondence between genes as compounds and chemical reactors, and chemical reactions is closer than is indicated in much of the legal literature. Both exhibit natural variability, un-predictability, which must be accommodated when the claims/scope of protection issue is decided on a case-by-case basis.[414] However, there is no clear evidence that past patent practice applied to chemical formulae is not a good template for evaluating genes as chemical

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[404] *Myriad*, 702 F. Supp. 2d at 141–43.
[405] Amicus Brief for the United States, *supra* note 13, at 16–17.
[406] *Myriad*, 702 F. Supp. 2d at 194.
[407] *Id.*
[408] 35 U.S.C. § 103(b) (2006).
[409] *Id.*
[410] GRUBB, *supra* note 41, at 246.
[411] 35 U.S.C. § 103(b).
[412] *In re* Marzocchi & Horton, 439 F.2d 220, 223 (C.C.P.A. 1971).
[413] *Id.* at 223.
[414] *Id.*

reactors. In this regard as well, genes are not unique and do not require special treatment as products of nature.[415]

C. Information as Utility

For the majority in *Myriad Appeal*, the informational dimension of a gene is relegated as a use; "[t]he claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and *their informational content is irrelevant* to that fact."[416] This perspective presents a pedestrian view of nature in which a component can have one and only one form. Nature is more complex than that. It appears as if the judges writing for the majority are unaware of the wave duality theorem, or do not see its possible applicability to this case.[417] Under this theory, light has simultaneously the attributes of particles and waves.[418] It is at one time observable as both a particle *and* a wave, depending on the perspective of the viewer.[419] The "de Broglie postulate" extends the theorem to all matter, although massive objects exhibit very short wavelengths so the duality has few practical implications.[420] By extension of the concept to genes, DNA can potentially be *both* a chemical compound and information bearing medium, depending on the perspective of the viewer. [421]

This interpretation does not mean, should not mean, that isolated DNA is inherently un-patentable subject matter, only that it has characteristics distinct from most compositions of matter which need to be recognized and considered when evaluating the claims, and claim scope in particular. That is, by focusing solely on the chemical form of a gene when deciding patentability fails to recognize that the claim scope can be very large, and overlapping if the scope of multiple patents extends to the protection of the same protein.

D. Claim Scope

It is suggested that the development of genetic research requires financial incentives, like the type provided by patents.[422] While true, and while the preceding argues against the need for a judicially-based product of nature patentability bar for any compositions of matter, including genes, it is also true that patents can be inhibitory to subsequent research and public welfare generally.[423] Those are the

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[415] Myriad Appeal, 653 F.3d 1329, 1375 (Fed. Cir. 2011).

[416] *Id.* at 1353 (emphasis added).

[417] *See id.*

[418] *See generally* DONALD A. MCQUARRIE, QUANTUM CHEMISTRY 30–36 (Univ. Science, 1983) (explaining the de Broglie equation).

[419] *Id.*

[420] *Id.*

[421] *See* Myriad, 702 F. Supp. 2d 181, 228–29 (S.D.N.Y. 2010).

[422] *See e.g.,* Graham, *supra* note 28 at, 1293–94, 1302–03 (explaining the results of a survey that found that biotechnology firms, a group encompassing those working on genomics, used patents more heavily than other areas of technology).

[423] *Myriad,* 702 F. Supp. 2d at 203–11.

concerns Judge Sweet used in ten pages of his decision to justify a summary judgment invalidating Myriad's fifteen claims. These concerns include: the costs, and profitability of the Myriad-monopoly screening, limiting access for some patients; Myriad's infringement lawsuits of several major university research and clinical programs' deficiencies and limited scope of Myriad's screening services; absence of confirmation reports and independent assessment for Myriad's screens compared with many other cancer screening tests; and critically the chilling and inhibitory effect of the Myriad patents over the BRCA1 and BRCA2 genes on research.[424]

Unsurprisingly, the Myriad council strongly contests many of these charges, noting in particular its policy of permitting scientists to conduct research on the BRCA1 and BRCA2 genes. Judge Sweet, in noting "the resolution of these disputes of fact and policy are not possible within the context of these motions" does not attempt a resolution of these differences of opinion.[425] In fact, the narrow research exemption under U.S. patent law makes such conflicts commonplace in rapidly evolving fields like genomics, but the human consequences in medicine could mean they are of far greater importance and visibility than in many other areas of technology. The Federal Circuit abstracted itself from this issue and emphasized that "[t]he issue before [the Court] is patent eligibility, not the adequacy of the patents' disclosure to support particular claims."[426]

Accordingly, the proper structuring of the balance between incentives and access hinges on appropriate claim construction, broad enough to provide the necessary incentives while narrow enough to minimize social costs, whether measured as resultant user fees or restricted access, delaying scientific advance. All of those factors are alleged as a consequence of the BRCA1 and BRCA2 patents.[427] Several researchers, including Professor Oskar Liivak, have tried their hand at establishing appropriate patent scope limitations.[428] Liivak's solution is to protect the inventor's specified gene sequence for encoding a protein, but the scope does not extend to an independently-discovered sequence, although the patented sequence may be used to verify the accuracy of the result.[429] That is, his proposal follows the pattern of copyright by allowing independent discovery, although there is some parallel with plant patents where establishing infringement requires a showing of direct copying.[430]

Adopting Liivak's approach, however, would require establishing a new *sui generis* system, which at minimum would be a very slow process. Rogers calls for limiting the scope to a particular DNA sequence and all DNA sequences surrounding the claimed sequence, especially if required to enable the invention.[431] Under this

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[424] *Id.* at 203–07.

[425] *Id.* at 211.

[426] Myriad Appeal, 653 F.3d 1329, 1354 (Fed. Cir. 2011).

[427] *Id.*

[428] *See generally* Liivak, *supra* note 41, at 199–201, 220–23 (exploring the effects of limiting claim scope in various types of patents).

[429] *Id.* at 182–83.

[430] *See id.*

[431] *See generally* Rogers, *supra* note 41, at 47–48, 50–56 (explaining how a DNA patent claim scope can be limited by claim interpretation, enablement and other legal considerations such as prosecution history estoppel).

approach, claims should be narrowed to the actual DNA molecules identified by the inventor rather than allowing claims over multiple versions of a sequence. [432]

This issue is of course not new to the courts under the specification requirement, although the legislative record has not been highly consistent.[433] For biological applications the leading Federal Circuit decision is *In re Wands*,[434] which applied to the detection of hepatitis B antigens using monoclonal antibodies.[435] The claims were rejected as the production of antibodies is unpredictable and unreliable, and hence requiring "undue experimentation."[436] Judge Smith approved consideration of eight factors including quantity, direction or guidance provided against the background of the state of the prior art.[437] Alternatively, in *Amgen* the issue was the claimed degree of purification.[438] The court ruled there was no evidence the inventor had actually produced the product using the disclosed method, the claimed degree of purity having been theoretically determined.[439] Additionally, in *In re Vaeck*,[440] the court quotes now deleted sections the Manual of Patent Examining Procedure ("MPEP") including sections 706.03(n) and 706.03(z).[441] In doing so, the Court rejected certain claims on the grounds that the disclosure was enabling only for claims limited in accordance with the specifications filed. [442]

There are no easy resolutions to the issue of the proper claim scope, including enablement, for gene patents. At the scientific level, an expanding knowledge of genomics and gene therapy will assist with an understanding of the level of experimentation required for broad claims, the numbers of genes encoding for proteins of similar functionality, and the business income requirements of gene therapy. This has largely occurred in the chemical sciences, but only over an extended period. In the legal realm, by Kenneth Burchfiel's reckoning:

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[432] *Id.*

[433] BURCHFIEL, *supra* note 391, at 181 ("These decisions are difficult to reconcile . . . ."). *See* 35 U.S.C. § 112 (2006).

[434] *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988).

[435] *Id.* at 733.

[436] *Id.* at 735.

[437] *Id.* at 736.

[438] Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1203 (Fed. Cir. 1991).

[439] *Id.* at 1214.

[440] *In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991).

[441] *Id.* at 492–93.

[442] *Id.* The Court concluded it is well settled that:

> [P]atent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. The disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a predictable factor such as a mechanical or electrical element.

Id. at 496.

> The decisions of the Federal Circuit relating to enablement . . . provide little guidance as to the suitable standards . . . with respect to such key questions as the appropriate definition of skill in the art, the criteria on which undue experimentation is based, the date on which enablement must be provided by the specification, and the use of post-filing work by others in the field to establish enablement.[443]

That key gap in the application of patent practice urgently needs attention from the USPTO and the Federal Circuit.

As an indication of the range of allowed claims scope for gene patents, Dr. Diana Sheiness used *Lexis* patent databases to determine the scope.[444] She used a four level standard for classifying claim scope where the narrowest applies only to the actual sequence claimed while the broadest covers sequences that may differ from the disclosed sequences, and that may not express the same protein.[445] The results indicated that the narrowest two categories constitute the majority of grants through 1994, but the proportion of broad grants has remained generally constant over the prior seven years.[446] Thus, broad gene claim scope may not be as significant an issue as is sometimes suggested.

As applied to the *Myriad* claims-in-suit though even Rogers' restrictive proposal of requiring claims to cover only gene sequences actually disclosed would affect but a single claim, claim 6 of the '492 patent.[447] And its exclusion would not resolve the use and access issues identified in the summary judgment depositions.

E. Discussion

The multiple notions of genes as "information" complicate the patentable subject matter issue. By one definition of information, the absence of utility is a clear bar to un-patentable compositions of matter.[448] By another, the product of nature debate is merely restarted from a slightly different perspective, and using a very deterministic, indeed simplistic, view of chemical reactions, the comparable by which gene patent applications are often evaluated.[449] At yet another level, case law has previously reconciled claims to both compounds and processes, which describes the dual nature of genes.[450] Evoking "information" in these ways in the product of nature debate applied to patents obscures rather than clarifies the issues. Where the "information" issue is relevant is in regards to the scope of protection, whether granting protection based on "their structure rather than their functions," read "information," as the Federal Circuit establishes, effectively extends the scope of protection beyond that characterized by the patented structure.[451] While it is compelling legally to separate

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[443] BURCHFIEL, *supra* note 391, at 179.
[444] Sheiness, *supra* note 69, at 121.
[445] *Id.* at 127–28.
[446] *Id.* at 133.
[447] Rogers, *supra* note 41, at 49–54.
[448] *Id.* at 28–29.
[449] *Id.* at 32–36.
[450] *Id.* at 26.
[451] Myriad Appeal, 653 F.3d 1329, 1353 (Fed. Cir. 2011).

structure and function, nature may not be obliging in the case of genes and the other increasingly esoteric areas coming before the USPTO.

At this relatively early stage in the development of genomics then, and lacking judicial guidance, it seems inappropriate to be establishing specific standards for gene patent claims. At the same time, prudence suggests since scope errors will occur that they be made on the side of too narrow rather than too broad. This prudence applies to genomics as to any rapidly evolving area of science in which lack of access to protected materials can have a particularly chilling effect on basic research.

What though of Myriad, the business? It has been said that Myriad is relying more on trade secrets and less on patents. Myriad used to share information on which of thousands of possible mutations in the BRCA genes actually caused cancer, but several years ago "quietly stopped contributing and cooperating, in favor of building its own database."[452]

IV. CONCLUSIONS

The preamble to these overall conclusions has been a lengthy one. Fortunately, the conclusions can be succinct and summarized below. However, before the specific conclusions, it is evident that what is missing throughout the debate has been an indication of Congressional intent. Intent has been interpreted various ways by multiple courts over time, but Congress has been largely silent on the product of nature issue. On one occasion there was a position stated on a closely related issue, which is revealing, this coming in the Plant Patent Act.[453] Therein Congress specifically and intentionally allowed Plant Patents for sports (bud variations) and mutants (seedling variation) leading to "an appearance or character distinct from that which normally characterizes the variety or species" whether encouraged (i.e., subjecting to x-rays) or naturally occurring, provided the plant exists in a cultivated state.[454] Clearly, Congress is stipulating in this instance that 'products of nature' be protectable even when the only human input, beyond general cultivation and asexual propagation) was to "recognize the new and appreciate its possibilities."[455] To some these new varieties or species might be products of nature, but not to Congress.

For sure the Plant Patent Act stipulated a *sui generis* system, with a justification given that each new variety is unique and could not be preserved without human effort. Congress, however, went beyond plants in drawing a parallel to chemistry:

> [f]urthermore, there is no apparent difference, for instance, between the part played by the plant organizer in the development of new plants and the part played by the chemist in the development of new compositions of

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[452] Andrew Pollack, *Despite Gene Patent Victory, Myriad Genetics Faces Challenges*, N.Y. TIMES BUS. DAY, (Aug. 24. 2011), http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?pagewanted=all.

[453] S. REP. No. 71-315 (1930).

[454] *Id.* at 3, 7.

[455] *Id.* at 7.

> matter which are patentable under existing law. Obviously, these new compositions of matter do not come into being solely by act of man. The chemist who invents the composition of matter must avail himself of the physical and chemical qualities inherent in the materials used and of the natural principals applicable to matter . . . . On the other hand, as is true of many of the most important inventions, he may accidentally discover the product, perhaps in the course of the regular routine of his work . . . . He may simply find the resulting product and have the foresight and ability to see and appreciate its possibilities and take steps to preserve its existence.[456]

The Supreme Court has observed, "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."[457] Previously by nearly two centuries in *Marbury v. Madison*[458] much the same conclusion had been reached.[459] Similarly, in the reports on the Plant Patent Act, Congress indicated that section 101 is to be interpreted broadly with no indication of a judicially created product of nature bar.

A. Products of Nature Generally

There is no need for a judicially defined product of nature patentability bar. In all cases—that is in all technology areas—patentability can be evaluated adequately by requirements set forth in the statutory sections 102, 103, and the first paragraph of section 112. The loosely delineated "product of nature" bar confuses rather than illuminates patentability considerations. The following sections list conclusions that are drawn from this article.

B. Patentability of Genes

1. Genes as Products of Nature

- There should be no product of nature patentability bar for genes in their various forms and configurations.

- The varied and loose terminology used in patents and by the courts unduly confuses the patentability issue. It seems preferable to use "DNA sequence" rather than the imprecise "gene." And "isolated DNA" needs a clearer definition. Scientists undoubtedly can propose other clarifying terminology in line with the current understanding of genetics.

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[456] *Id.*
[457] Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).
[458] Marbury v. Madison, 5 U.S. 137 (1803).
[459] *Chakrabarty*, 447 U.S. at 314.

2. Genes as Information

- Two distinct approaches to the "genes as information" issue, one leading directly to a lack of specific novelty and one raising again the entire product of nature debate from a different but unhelpful dimension, can be excluded as redundant.

- In general, patent practice as currently applied to chemicals is an appropriate model for evaluating genes, and one strongly endorsed by the appeals court. Many chemical reactions exhibit the same kinds of variability which is observed in the expression of molecules by genes so by that dimension as well the chemical model is applicable.

- Case law has previously considered and reconciled the relationship between compositions of matter and processes, and there is no reason why similar considerations cannot be applied to accommodate the multifunctional nature of genes in that context.

- The Federal Circuit's use of "information" has yet another context, which relates directly to the scope issue.

3. Scope of Gene Patent Claims

- Gene patents claim scope often does not correspond with the degree of specification.

- Greater judicial direction is required to clarify further the enablement issue. Lacking that, a general stipulation of gene patent claim scope is premature.

- At the same time a better scientific understanding of genomics is required for a deeper comprehension of claim scope and enablement. It will take considerable time to achieve the degree of scientific command now applied to chemical patents.

- For now with a rapidly evolving and critical scientific area like genomics it is prudent to be cautious about scope, to err as it were on the side of too narrow rather than too broad. In practice this can be applied as limiting claims to DNA sequences actually identified.

C. The Myriad Claims-in-Suit

- The general conclusion here is that the *Myriad* composition of matter claims are patentable subject matter and should be allowed.

- The DOJ argues for allowing thirteen of the fifteen claims-in-suit, with the two remaining being neither process claims nor those reading to cDNA (a man-made product) while the Federal Circuit sees all forms of isolated DNA as patentable subject matter due to a distinct chemical structure.

- Only one of the two (claim 6 from the '492 patent) is excessively broad and should be limited to the sequences actually identified.

- The process claim issues lie outside the product of nature focus of this analysis, but seem easily resolved by a small change in claim language.

Overall, the Myriad issue represents a minor tempest, but it is also a clear indication of how complex new compositions of matter cannot be treated as the same old static chemical substances. Genes may not be products of nature in the legal sense, but they do reflect the complexity of much in nature and science; complexity which must be recognized and incorporated into patenting decisions.