METAPHOR AFTER *MYRIAD:* THE EFFECT OF LEGAL RHETORIC ON INTELLECTUAL PROPERTY PROTECTION FOR BIOLOGICAL SEQUENCES

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"Nature is there no one of entities,
But merely mixture and of things mixed,
A change, and thus by men is Nature styled."[1]

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[1] ARISTOTLE, THE METAPHYSICS 118 (John H. McMahon trans., George Bell and Sons 1896) (quoting Empedocles).

INTRODUCTION

The *Association for Molecular Pathology v. Myriad Genetics* (*Myriad*), the U.S. Supreme Court's first code-level determination of patent eligibility for biological sequences,[2] ultimately barred isolated DNA patents in the United States while granting patent protection of cDNA.[3] *Myriad*'s decision has, since 2013, continued to pose questions regarding legal protection for biological sequences as a whole: which types of biological sequences are patent-ineligible, and what legal strategy organizations should use to protect these sequences.[4] As biotechnology companies

[2] The term "biological sequences" is used to generalize the type of data to be protected. Because data used could include more than just DNA, including proteins coded by DNA, RNA, single nucleotide polymorphisms (SNPs), genes, or other variations, it is critical to acknowledge this wide variety when determining appropriate legal protection for such data.

[3] The *Association for Molecular Pathology v. Myriad Genetics* case involved actions of Myriad Genetics, LLC, a biological testing corporation that provides genetic testing, in part to determine genetic probability of breast cancer (BRCA1 and BRCA2). *See infra* Parts I.C. & I.E.

[4] Although the *Myriad* case was decided in 2013, a subsequent ancillary complaint submitted to the Department of Health and Human Services (HHS) has brought legal protection for biological sequences into the forefront once more, representing individuals seeking access to genetic information as medical records under the Health Insurance Portability and Accountability Act (HIPAA). *See ACLU Files Complaint Against Lab That Refuses to Recognize Patients' Rights to Their Own Genetic Information*, AMERICAN CIVIL LIBERTIES UNION, (May 19, 2016), https://www.aclu.org/news/aclu-files-complaint-against-lab-refuses-recognize-patients-right-their-own-genetic-information [https://perma.cc/BR9T-S5FE]. According to the ACLU, Myriad Genetics has received patient requests but is resisting providing information to individuals based on the proprietary nature of its database in violation of HIPAA. *Id.* HIPAA is a relatively complex and specific piece of legislation, so it is unclear how this complaint will be resolved, but the evidence of this type of complaint illustrates the

continue to perform genetic testing and market pharmacogenomics products to the general public, the industry will likely demand appropriate legal instruments to safeguard significant investment in research and development. Although no clear direction has emerged for protecting biological sequences holistically, analyzing metaphors used in the *Myriad* decision may suggest a legal direction compatible with court reasoning. Based on metaphors used most prevalently in *Myriad,* courts seem to suggest thin compilation copyright and trade secret protection offer potential solutions for legally protecting biological sequences.

Part I describes the history of biotechnology research and commercialization to provide a backdrop for understanding the unique nature of the market. Part II introduces an Aristotelian approach to legal (forensic) persuasive communication, a lens for analyzing the *Myriad* case. In Part III, this Author applies an Aristotelian rhetorical analysis to the *Myriad* case, identifying trends in metaphor usage and word choice, across and within each court hearing the case. Part IV leverages the *Myriad* analysis to review potential legal instruments available to protect patent-ineligible biological sequences, in particular trade secret protection, thin copyright (compilation) protection, and database protection.

I. HISTORY OF DNA RESEARCH AND COMMERCIALIZATION

Genetic research and development is largely a late Twentieth Century business venture. Although genetic research began in the late 19th Century after the discovery

continued need for understanding the legal status of biological sequences like DNA testing results and associated compilations of such results, as in a database.

of deoxyribonucleic acid (DNA) in 1869,[5] the structure and function of DNA largely eluded researchers until Rosalind Franklin produced the first crystalline DNA x-ray in 1952,[6] and James Watson and Francis Crick subsequently identified DNA's structure in 1953.[7] Watson and Crick had discovered the chemical structure of DNA, a double-helix of nucleotide base pairs[8] with a phosphate diester, helical backbone.[9] The nucleotides included coding and non-coding nucleotides,[10]

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[5] VICTORIA SHERROW, JAMES WATSON & FRANCIS CRICK, DECODING THE SECRETS OF DNA 101 (1995) (stating Johann Friedrich Miescher discovered the first evidence of DNA in 1869).

[6] JAMES D. WATSON, THE DOUBLE HELIX: A PERSONAL ACCOUNT OF THE DISCOVERY OF THE STRUCTURE OF DNA 168 (Touchstone 2001) (1968). *See generally* BRENDA MADDOX, ROSALIND FRANKLIN: THE DARK LADY OF DNA (2002) (describing Rosalind Franklin's account of the discovery of DNA). Rosalind Franklin had originally produced an x-ray that seemed to propose a triple helix, and this information was used by James Watson and Francis Crick to begin developing a chemical model for DNA.

[7] *Id*. at 228.

[8] *See* KARL A. DRLICA, DOUBLE-EDGED SWORD: THE PROMISES AND RISKS OF THE GENETIC EVOLUTION 161 (1994).

[9] VICTOR R. MCELHENEY, WATSON AND DNA: MAKING A SCIENTIFIC REVOLUTION 58 (2003).

[10] *See*, *e.g*., AB Rose, *Intron-mediated Regulation of Gene Expression*, 326 CURR. TOP. MICROBIOL. IMMUNOL. 277 (2008); Caroline Goebels et al., *Introns Regulate Gene Expression in Cyptococcus neoformans in a Pab2p Dependent Pathway*, PLOS GENETICS (Aug. 15, 2013), http://journals.plos.org/plosgenetics/article?id=10.1371/journal.pgen.1003686 [http://dx.doi.org/10.1371/journal.pgen.1003686]. Recent research has shown that introns may play more of a role than previously thought in the expression of genes, even though mRNA cuts introns during DNA replication. This may mean that biological sequences that do include introns, may actually be more valuable for successive research than cDNA.

exons and introns,[11] respectively, though the nucleotides themselves included all of the information needed to reproduce a cell with a specific set of genetic instructions.[12] This discovery led to the often used metaphor "code of life" to describe DNA,[13] one of many metaphors used prolifically in science.[14]

A. DNA Research

DNA's natural duplication process inspired researchers to intervene and begin mapping the genome, or the series of human features represented in the nucleotides themselves. From the early 1980s through the 1990s, the invention of basic computerized sequencing technologies improved genetic testing dramatically.[15] In particular, the

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[11] ROBERT J. BROOKER, GENETICS: ANALYSIS AND PRINCIPLES 325 (1999).

[12] *See* MCELHENEY, *supra* note 9, at 50.

[13] Katrin Weigmann, *The Code, the Text, and the Language of God*, 5 EMBO REP. 116, 116–18 (2004) (noting "Code" has been used for some time to describe science, probably first by Schrödinger in his 1944 book, *What Is Life?* and echoed in Watson and Crick's description of their own work).

[14] Patrick S. O'Donnell, *Analogy & Metaphor: An Idiosyncratic Introduction* (2011), http://www.ssrn.com/abstract=1804987 [https://perma.cc/E327-9P3C]. Examples include the Rutheford-Bohr hydrogen atom "solar system" and the "crust" floating on the fluid mantle of the Earth.

[15] Peter Diamond, *Cancellation of the Archon Genomics XPRIZE: A Public Debate*, ARCHON GENOMICS, XPRIZE WEBSITE BLOG, (Mar. 27, 2014) http://genomics.xprize.org/blog/2014/03/27/cancellation-archon-genomics-xprize-public-debate [https://perma.cc/S29B-7P46]. Sequencing technologies improved functionality at a rapid pace, in line with the computer revolution, reducing size and increasing speed. *Id.* In 2006, the X Prize Foundation for Archon Genomics launched a competition to see which inventor could build a sequencer that could sequence 100 genomes in 30 days or less, with no more than one base pair error per one million base pairs sequenced. *Id.* The award of $10

method of artificially unzipping and amplifying the double-helix for purposes of isolating specific genes through polymerase chain reaction (PCR),[16] and the use of messenger RNA (mRNA) and base pairs in the laboratory to create complementary DNA (cDNA) based on the natural DNA transcription and translation processes effectively commercialized DNA use.[17] Isolated DNA, physically

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million dollars was set to be given at the end of 2013, but instead market investment and technology outpaced the expectations in 2006, with the sequencing market increasing 62%, compounded annually, per year between 2006 and 2011. *Id.* In 2013, the global sequencing market had increased to $1.4 billion in sequencing and reagent sales. At the time of the 2013 press release, organizations could sequence an entire human genome for $1,000 dollars in a few days. *Id.*

[16] DRLICA, *supra* note 8, AT 171–73; 454 LIFE SCIENCES, *History of Genome Sequencing* (2006), http://www.454.com/downloads/news-events/history-of-genome-sequencing_FINAL.pdf [https://web-beta.archive.org/web/20160313110511/http://www.454.com/downloads/news-events/history-of-genome-sequencing_FINAL.pdf]. Frederick Sanger's Sanger Sequencing method in 1976 opened the door to more modern sequencing methods, including Polymerase Chain Reaction (PCR), invented by Kary Mullis in 1983. *Id.* These models enabled sequencers to amplify and focus in on specific DNA regions. *Id.* Additional sequencing methods would eventually be invented, including MPSS and pyrosequencing. 454's first version of a machine using next-generation pyrosequencing improved efficiency of sequencing by six times. *Id.*

[17] *Reverse Transcription (cDNA Synthesis)*, NEW ENGLAND BIOLABS, INC., https://www.neb.com/applications/cloning-and-synthetic-biology/dna-preparation/reverse-transcription-cdna-synthesis [https://perma.cc/VKH5-HZ8G] (last visited Mar. 19, 2017); SMITHSONIAN INSTITUTION ARCHIVES, RU 9577, *The History of PCR* (2004), http://siarchives.si.edu/research/videohistory_catalog9577.html [https://perma.cc/35KB-VPX2]. PCR involves the use of mRNA and cDNA, and eventually was commercialized, first in 1989 by Cetus Corporation, after engineers converted a formerly time-intensive manual process to using the DNA Thermal Cycler, in partnership with Perkin-Elmer Corporation. *Id.* After some years of inquiry, Roche

removed and chemically cleaved from surrounding DNA, could be used as a primer, probe, or template, key functions necessary for genetic testing services.[18]

In 1988, not long after Congress passed the Bayh–Dole Act,[19] the Human Genome Project (HGP) began with the goal of mapping the entire human genome, three billion base pairs.[20] Early in HGP's development, private companies like Celera Genomics sought to privatize the genetic information discovered,[21] in part because the HGP

Molecular Systems purchased the PCR patent and technology for $300 million. *Id.*

[18] *Polymerase Chain Reaction*, MCGILL SCHOOL OF COMPUTER SCIENCE, http://cs.mcgill.ca/~rwest/wikispeedia/wpcd/wp/p/Polymerase_chain_reaction.htm [https://perma.cc/S59Y-RPQ7] (last visited Mar. 19, 2017). Primers are typically used in PCR to identify the beginning and end of the sequence identified. *Id.* This is a critical process prior to amplifying and sequencing a specific length of nucleotides for the purpose of clinical diagnosis. *Id.* Geneticists also give probes radioactive labeling to pinpoint mutation markers. *Id.* They work by identifying complementary base pairs to the mutation in the probe itself, identifying the presence or absence of mutation markers. *Id.*

[19] Charles R. McManis & Sucheol Noh, *The Impact of the Bayh–Dole Act on Genetic Research*, UNIVERSITY OF CALIFORNIA BERKELEY SCHOOL OF LAW (Aug. 13, 2006), at 2–3, https://www.law.berkeley.edu/files/mcmanis(1).doc. The purpose of the Bayh–Dole Act was to stimulate commercial investment in the scientific enterprise. *Id.* The timing of the HGP not long after the Bayh–Dole Act has caused many to speculate whether the HGP was originally conceived with private application (and associated intellectual property rights) in mind. *Id.*

[20] EDWARD EDELSTON, FRANCIS CRICK & JAMES WATSON AND THE BUILDING BLOCKS OF LIFE 94 (1998).

[21] David E. Korn, *Patent and Trade Secret Protection in University-Industry Research Relationships in Biotechnology*, 24 HARV. J. ON LEGIS. 191, 231–34 (1987). Developments in cooperative relationships for the biotechnology field between academia and corporate sponsors has shifted biotechnology development towards commercial ventures, bringing legal protection for these investments into sharper focus,

required significant investment in genome sequencing equipment and physical space, as well as labor costs to run the machines and collect the data.[22] Many private companies planned an aggressive course to transform the pharmaceutical and medical fields using DNA, rather than chemistry, to diagnose, treat, and cure genetic diseases and expected limited monopolies on these developments. Evidence of these expectations proved out in the open market: significant growth significantly outpacing public investment[23] and a dramatically increasing number of private DNA patents.[24] By 2001, the HGP had sequenced the entire human genome, marking an important

especially the concepts of secrecy and private use of publicly funded research. *Id.*

[22] *See* McManis & Noh *supra*, note 21 (noting sequencing in the 1970s costs five dollars per base pair); *see also* Peter Gorner, *Public-private Battle over Gene Code Heats Up*, CHICAGO TRIBUNE (Mar. 12, 2000), http://articles.chicagotribune.com/2000-03-12/news/0003120235_1_celera-genomics-corp-human-genome-project-genome-database (noting that the debate over ownership rights to data is not a new; during the HGP, multiple private firms sought to privatize data collected, with hopes of creating commercial products, and this concern has continued over the past fourteen years).

[23] Ilse R. Wiechers, Noah C. Perin & Robert Cook-Deegan, *The Emergence of Commercial Genomics: Analysis of the Rise of a Biotechnology Subsector during the Human Genome Project, 1990–2004*, 5 GENOME MEDICINE 83, at 2–5 (2013), http://genomemedicine.com/content/pdf/gm487.pdf [https://perma.cc/FN2K-49GE] (noting that between 2,500 and 4,500 DNA patents were filed every year between 1998 and 2012, with genomic firm capitalization hitting a peak in 2000 of nearly 90 billion dollars).

[24] *Id.* at 3–5.

development in biotechnology's ability to pinpoint the location or locations of mutations causing genetic diseases.[25]

B. Gene Identification

Of course, the biotechnology field's work had only just begun. Some genetic disorders affect multiple genes, involving up to 249 million nucleotides.[26] Certainly, the process of locating the correct, comparatively short genetic sequence, from ten nucleotides for probes to tens of thousands for primers and templates, within hundreds of millions of nucleotides is tremendously time-consuming. As a result, biotechnology's investment in locating just one gene has required hundreds of millions of dollars in investment,[27] and prior to the *Myriad* decision, the United States Patent and Trademark Office (USPTO) had commenced review for lab-created derivatives of human

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[25] Andrew Edgar, *Genetic Information and Public Opinion*, THE GOVERNANCE OF GENETIC INFORMATION: WHO DECIDES? 178 (Heather Widdows & Caroline Mullen eds., 2009).

[26] NATIONAL INSTITUTES OF HEALTH, *What are Complex or Multifactorial Disorders?* U.S. NATIONAL LIBRARY OF MEDICINE (Oct. 18, 2016), https://ghr.nlm.nih.gov/primer/mutationsanddisorders/complexdisorders [https://perma.cc/98EM-44KD]; Chandana Tikiri Bandara Tennakoon, *Fast and Accurate Mapping of Next Generation Sequencing Data* 12 (2013) (unpublished Ph.D. dissertation, NUS Graduate School for Integrative Sciences and Engineering National University of Singapore) (on file with the National University of Singapore), http://www.scholarbank.nus.edu.sg/bitstream/handle/10635/53713/TennakoonCTB.pdf?sequence=1 (describing the necessity for faster sequencing, as Chromosome 1 has 249 million base pairs).

[27] Miri Yoon, *Gene Patenting Debate: The Meaning of Myriad*, 9 J. MARSHALL REV. INTELL. PROP. L. 953, 974 (2010). According to Yoon, invalidating gene patents will result in the "unraveling of the biotechnology industry," destroying decades of research investment and funding.

genes, including isolated DNA and cDNA.[28] Many early biotechnology companies began patenting isolated DNA and cDNA immediately to protect their investments.[29]

C. Isolated DNA and cDNA

Myriad Genetics entered the biotechnology scene after the Bayh–Dole Act encouraged technology commercialization between universities and commercial entities. Myriad's product set started with discovery of the BRCA1 gene by Mary-Claire King, one of the genes for breast cancer, followed by Myriad sequencing and patenting the gene in 1994, subsequently creating a testing product to diagnose breast cancer.[30] In 1996, Myriad further developed a gene discovered by Michael Stratton, the BRCA2 gene, sequencing and patenting lab-created versions of BRCA2.[31] Genetically testing for both genes together, along with a later-developed test, the BART, provided a reasonably

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[28] *Public Hearing on Genetic Diagnostic Testing*, U.S. PATENT AND TRADEMARK OFFICE (Alexandria, VA, Feb. 16, 2012), at 34, https://www.uspto.gov/sites/default/files/aia_implementation/120216-genetic_transcript.pdf [https://perma.cc/4E9W-RATF](describing the USPTO's Manual of Patent Examination and Procedure applying to DNA patent examination).

[29] Art Berkowitz & Daniel J. Kevles, *Patenting Human Genes: The Advent of Ethics in the Political Economy of Patent Law*, WHO OWNS LIFE? (David Magnus et al. eds., 2002). Initially, it was the National Institutes of Health (NIH) that sought to patent genetic sequences, due to the enormous financial incentives via the Federal Technology Transfer Act of 1984, and the idea is generally attributed to the patent attorney from Genentech, Max Hensley. *Id.*

[30] *BRCA Briefing Page*, IGSP CENTER FOR GENOME ETHICS, LAW & POLICY (2014), http://www.genome.duke.edu/centers/cpg/Myriad/ [https://web-beta.archive.org/web/20150225222502/http://www.genome.duke.edu/centers/cpg/Myriad/].

[31] E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS IN MED. S39 (Apr. 1, 2010).

reliable test for breast cancer predisposition, and Myriad charged up to $3700 dollars for the complete service.[32]

D. Commercialization

The USPTO had issued between 2,645 and 5,000 patents claiming isolated DNA inventions before the *Myriad* decision.[33] By 2005, the USPTO had granted 40,000 total DNA patents covering 20% of the human genome, of which 65% was owned or licensed by the private sector.[34] The biotechnology industry has done well with no evidence of negative impact on innovation, with the global biotechnology industry forecasted to be worth $414.5 billion by 2017.[35] Despite this forecast, biotechnology typically outlays significant research and development investment, which is often spread over a protracted timetable with uncertain return.[36]

The promise of limited monopoly in patent protection seems to have increased research and market investment in the biotechnology sector.[37] Despite Myriad's

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[32] *Id.*

[33] *Compare* Ass'n for Molecular Pathology v. U.S. Pat. and Trademark Off., 653 F.3d 1329, 1355 (Fed. Cir. 2011) *with* Gregory D. Graff et al., *Not Quite a Myriad of Gene Patents*, 31 NATURE BIOTECH. 404 (2013).

[34] *See* Graff, *supra* note 33.

[35] Transparency Market Research, *Global Biotechnology Market to Value USD 414.5 Billion 2017: Transparency Market Research*, PR NEWSWIRE (Sept. 24, 2014), http://www.prnewswire.com/news-releases/global-biotechnology-market-to-value-usd-4145-billion-2017-transparency-market-research-276915571.html [https://perma.cc/3BY8-T6PE].

[36] Jordan Moliver, *Non-Possession as One-Tenth of the Law: Right to Refuse or Duty to Deal in Molecular Monopolies*, 14 COLO. TECH. L.J. 371, 385 (2016).

[37] Kevin Noonan, *Ignore the DNA Patent Scaremongers*, U.S. NEWS & WORLD REPORT (June 10, 2013), http://www.usnews.com/opinion/

patent protection and $200 million investment in producing marketable versions of the BRCA1 and BRCA2 genes,[38] over 18,000 scientists have conducted research using the genes and have published more than 7,000 papers.[39] Historically, patent portfolios have enabled biotechnology firms to attract investment dollars for future research and growth.[40]

However, the threat of DNA patent problems and conflicts of interest loomed: although scientists preferred open access to data for research purposes, many scientists also enjoyed financial benefits from patents.[41] Many publicly acknowledged that although a lack of legal protection could financially damage the biotechnology sector,[42] too many patents may prevent scientists from using isolated DNA and cDNA to develop more efficient and higher quality diagnostic procedures for genetic diseases, and historically high testing costs resulting from patent monopolies could impact patient access to these potentially life-saving procedures.[43] By 2009, both scientists and the

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articles/2013/06/10/patenting-dna-spurs-innovation [https://perma.cc/KYH5-4HXZ].

[38] Ass'n for Molecular Pathology v. U.S. Pat. and Trademark Off., 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[39] *Id.*

[40] Nicole Boutros, *Race to the Cure: Why Gene Patents Pave the Way for Breast Cancer Research*, 19 AM. U. J. GENDER SOC. POL'Y & L. 1009, 1030 (2011).

[41] Joanna K. Sax, *Financial Conflicts of Interest in Science*, 21 ANNALS HEALTH L. 291, 325 (2012).

[42] *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 190–92.

[43] *See, e.g.*, Tiana Leia Russell, *Unlocking the Genome: The Legal Case against Genetic Diagnostic Patents*, 16 MARQ. INTELL. PROP. L. REV. 81, 112–13 (2012); Elizabeth A. Rowe, *Patents, Genetically Modified Foods, and IP Overreaching*, 64 SMU L. REV. 859, 892 (2011); Douglas L. Rogers, *Coding for Life: Should Any Entity Have the*

general public had strongly opposed the patenting of human gene products.[44]

E. History of Association for Molecular Pathology v. Myriad Genetics

In 2009, as a result of Myriad attempting to enforce its patents, multiple entities organized with the sole purpose of invalidating patents on Myriad's BRCA1/2 gene patents. Scientists and public advocates argued that breast cancer testing should be available to all at reasonably competitive prices, and the patents should be invalidated: Patenting isolated DNA and lab-created cDNA would likely create a chilling effect on breast cancer research.[45] Rhetoric surrounding the discussion included some commentators remarking that "patenting DNA" would constitute "patenting our bodies," and by living, humans could infringe

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Exclusive Right to Use and Sell Isolated DNA?, 12 U. PITT. J. TECH. L. & POL'Y 1, 61–62 (2011); Elle Marino, *A Look at the Technical, Social, and Economic Considerations behind Gene Patents*, 22 KAN. J. L. & PUB. POL'Y 299, 312–15 (2013).

[44] *See, e.g.*, *Gene Patenting*, AM. MED. ASSOC. (2014), https://www.ama-assn.org/delivering-care/gene-patenting [https://perma.cc/AS2P-4APW] (last visited Mar. 19, 2017) (stating the AMA's opposition to gene patenting); *AMP v. Myriad: Gene Patents*, PUBLIC PATENT FOUNDATION (May 12, 2009), http://www.pubpat.org/brca.htm [https://perma.cc/WL42-URWG] (stating the PPF's opposition to gene patenting in *Myriad*); *The Fight to Take Back Our Genes*, ACLU, https://www.aclu.org/fight-take-back-our-genes [https://perma.cc/QH9L-HT53] (last visited Mar. 19, 2017) (stating that Myriad Genetics "owns" genes in your body and the dangerous implications for health and research); Jesse Reynolds & Marcy Darnovsky, *The Battle to Patent Your Genes*, THE AM. INTEREST (Sept. 1, 2009), http://www.the-american-interest.com/articles/2009/09/01/the-battle-to-patent-your-genes/ [https://perma.cc/TC4A-YV48] (observing the lack of discussion around social and ethical implications of patenting genes).

[45] *Id*.

patents.[46] The BRCA advocacy group, led and financed primarily by the ACLU, filed a complaint in 2009 to invalidate Myriad's BRCA1 patent, BRCA2 patent, and methods claims based on 35 U.S.C. § 101 ('101'),[47] which defines patent subject matter eligibility.[48] In November 2010, after sharp public criticism, the United States Department of Justice (DOJ) also filed a brief stating that biological sequences should not be patent-eligible.[49]

In *Myriad*, the District Court for the Southern District of New York (District Court), the Court of Appeals for the Federal Circuit (Federal Circuit), and the United States Supreme Court (Supreme Court) evaluated the patent eligibility of biological sequences claims under 101. Under 101, subject matter is eligible for patent protection, as long as it is a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[50] Drafters of 101 had included as a protected category "composition of matter," which has become a very broad category for patent eligibility, including manmade chemicals, purified biochemicals, alloys, and, most

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[46] *Id*. The rhetoric of patenting "my" genes, that an organization could patent naturally occurring genes in a person's body, was extremely effective, though technically inaccurate from a genetics perspective (cDNA and isolated DNA are created from a variety of DNA sequences to create something usable that can identify a genetic disorder in multiple individuals, not just take and use one person's DNA). *Id.*

[47] 35 U.S.C. § 101 (2012).

[48] Sandra Park, *Myriad's Latest Attempt to Maintain Its Monopoly on Our Genes Rejected*, ACLU (Mar. 12, 2014), https://www.aclu.org/blog/tag/gene-patenting [https://perma.cc/PH5Z-YK2K].

[49] Heidi Lexford, *US Government Wants Limits on Gene Patents*, NATURE (Nov. 2, 2010), http://www.nature.com/news/2010/101102/full/news.2010.576.html [https://perma.cc/V74B-7TF6].

[50] Daniel J. Klein, *The Integrity of Section 101: A "New and Useful" Test for Patentable Subject Matter*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 287 (2011).

significantly, biological sequences.[51] Because 101 is broadly drafted, federal courts developed several common law exceptions,[52] including the law of nature exception articulated as "an abstract idea, natural phenomenon, or law of nature," a flexible concept gaining greater attention following the *Myriad* decision.[53]

In 2010, the District Court invalidated Myriad's gene and methods patents in summary judgment, and Myriad appealed to the Federal Circuit.[54] In a split 2011 decision, Judge Lourie and Judge Moore upheld all claims under 101, though Judge Moore expressed some concern regarding lengthy biological sequences with limited utility compared to shorter, probe-length sequences used for a variety of lab and diagnostic purposes.[55] Judge Bryson concurred with the holding on cDNA eligibility and methods claims, but dissented on eligibility for isolated DNA, focusing heavily

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[51] Eric A. Stone, Jennifer H. Wu & Jenny C. Wu, *What Is Patentable? Making Sense of Section 101*, FED. LAW., Oct.–Nov. 2013, at 24, 26.

[52] *Id*. at 27–28; s*ee also* 69 C.J.S. *Patents* §§ 26, 30 (noting laws of nature may not be protected under patent law, and typically this requires some "transformative" steps or manipulation central to patent claims); *see also* 1 BIOTECH. AND THE LAW § 3:1–12 (June 2013).

[53] Peter Lee, *The Supreme Court's Myriad Effects on Scientific Research: Definitional Fluidity and the Legal Construction of Nature*, 5 U.C. IRVINE L. REV. 1077 (2015); Matthew M. Karlan, *Patent Policy, Natural Products, and the Gene Patent Debate: Seeking the Proper Judicial Mode of Analysis*, 67 N.Y.U. ANN. SURV. AM. L. 95, 134 (2011) (arguing that the Constitutional mandate to advance technology offers a guiding principle for the evaluation of natural products and overall policy, and that courts have no legitimate basis through Constitutional provisions to employ public policy arguments regarding patent protection of natural products based on morality).

[54] Ass'n for Molecular Pathology v. U.S. Pat. and Trademark Off., 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[55] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 653 F.3d 1329 (Fed. Cir. 2011).

on the process of creating isolated DNA: cleaving or separating a segment of DNA by breaking its covalent bonds, then adding an additional chemical unit to each end (i.e. a carboxyl group).[56] Bryson reasoned that the human activity involved in segmenting DNA and improving utility was incidental to segmentation itself, not an inventive act.[57] Both Myriad and the ACLU petitioned the Supreme Court for certiorari.[58]

In 2012, the Supreme Court decided *Mayo v. Prometheus*, a patent case involving a methods patent based on natural processes,[59] and remanded *Myriad* back to the Federal Circuit for review in light of the *Mayo* decision.[60] The Federal Circuit reconsidered Myriad's methods patent claims and referenced *Mayo*, but otherwise maintained their reasoning regarding cDNA and biological sequences, cutting and pasting passages directly from the original Federal Circuit ruling.[61]

In 2012, the Supreme Court granted certiorari and decided the case in June 2013.[62] In addition to Myriad

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[56] *Id*.

[57] *Id.*

[58] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107 (2013).

[59] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).

[60] Angela L. Morrison, *Mayo v. Prometheus: Patent Eligibility of Claims Covering Natural Laws*, 41 COLO. LAWYER 77, 81–82 (2012). Practitioners should not rely primarily on showing transformation by drafting administering steps in claim language. After *Prometheus*, claims have to do "significantly more than describe natural laws." *Id.* at 80.

[61] Ass'n for Molecular Pathology v. U.S. Pat. and Trademark Off., 689 F.3d 1303, 1329 (Fed. Cir. 2012).

[62] *Ass'n for Molecular*, 133 S.Ct. at 2115 (2013).

Genetics and the ACLU's involvement, the Department of Justicw, as an independent party, argued for a mixed approach: allow cDNA (as fully lab-created) patent-eligible and consider isolated DNA patent-ineligible.[63] Amid a flurry of metaphors in oral argument, and considering only the patentability of cDNA and biological sequences, the Supreme Court upheld the Federal Circuit's holding for cDNA as patent subject matter eligible and overruled the Federal Circuit's split holding for biological sequences, holding that biological sequences are not subject matter eligible.[64]

The impact of this decision is still murky, although financial performance data may now indicate the impact of the *Myriad* decision on Myriad Genetics, including a 26% loss in 2016, down $30 million from Wall Street's estimate.[65] While the biotechnology market did not

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[63] *US Supreme Court Strikes Down Gene Patents but Allows Patenting of Synthetic DNA*, GENOMEWEB (Jun. 13, 2013), https://www.genomeweb.com/clinical-genomics/us-supreme-court-strikes-down-gene-patents-allows-patenting-synthetic-dna [https://perma.cc/CM83-Z7SB].

[64] *Ass'n for Molecular Pathology*, 133 S.Ct. at 2111; *see* Joseph S. Classe, *Genes and the Supremes: Will the Supreme Court Uphold Patents for Isolated Gene Sequences?*, 45 TEX. TECH L. REV. 533, 542–43 (2013). In the past, Congress had opportunities to weigh in on genetic protection, for example in the Genomic Research and Accessibility Act (GRAA), which would have prevented patents on any nucleotide sequences, functions, or correlations. *Id.* When Congress had an opportunity to articulate patent conditions for genetic sequences while drafting the America Invents Act, instead Congress only required a study to determine effects of second opinion genetic testing on existing patent holders. *Id.* It remains to be seen whether Congress takes the opportunity following *Myriad* to communicate a stronger message around patent eligibility. *Id.*

[65] Maxx Chatsko, *Here's Why Myriad Genetics is Down 26% in 2016*, THE MOTLEY FOOL (July 21, 2016), http://www.fool.com/investing/2016/07/21/heres-why-myriad-genetics-is-down-26-in-2016.aspx [https://perma.cc/586Y-3678]; Amy Reeves, *Myriad Genetics Stock*

immediately respond negatively to the Supreme Court decision,[66] biotechnologists rely on proprietary use of biological sequences in a wide variety of genetic testing processes, including primers, probes, and templates, which are key elements of PCR.

F. Method for Examining Association for Molecular Pathology v. Myriad Genetics

Post-*Myriad*, continuing investment in biotechnology for clinical testing and pharmacogenomics likely requires some legal protection to safeguard products of investment for private industry.[67] In order to determine which alternate legal approaches may provide a level of protection for other patent-ineligible biological sequences and better understand the analytical processes used to determine biological sequence patent eligibility, this Author identified metaphors used in the *Myriad* case, from complaint to Supreme Court decision. To reveal the underlying jurisprudential decision-making process underlying the linguistic delivery of the decision, an Aristotelian *forensic topoi* was used to identify and

Craters as Competition Surprises Wall Street, INVESTOR'S BUSINESS DAILY (Aug. 10, 2016), http://www.investors.com/news/technology/myriad-genetics-stock-craters-as-competition-surprises-wall-street/ [https://perma.cc/G253-QPEL].

[66] Dan Magan & Bertha Coombs, *High Court's Ruling on DNA Could Boost Biotech*, CNBC (June 13, 2013), http://www.cnbc.com/id/100814209 [https://perma.cc/VN97-357S].

[67] PETER W. HUBER, THE CURE IN THE CODE: HOW 20TH CENTURY LAW IS UNDERMINING 21ST CENTURY MEDICINE 88 (2013). Pharmacogenomics, or the study of medicines that target genes, reduce side effects, or work most effectively with specific genetic structures. *Id.*

categorize metaphors used to understand DNA sequences and determine legal status under 101.[68]

II. ARISTOTELIAN RHETORIC AND LEGAL REASONING

Aristotelian concepts of legal argumentation are considered foundational to modern legal argumentation. Although scholars have reviewed the concept of metaphor in legal analysis for some time, often metaphor is described as a linguistic construct, rather than a tool deliberately used to understand deeper meaning and formulate decisions via inductive reasoning by analogy. The use of Aristotle's *enthymeme*, the foundation of persuasive linguistics for Aristotle, also provides a vehicle for use of metaphor in modern jurisprudence.

A. Foundation of Research Method: Logical Proofs for Argumentation

Aristotle developed the foundation of modern legal argumentation through his *Topics* and *Prior Analytics via* analytical processes of *syllogismos* (deductive reasoning, the syllogism, or complete reasoning)[69] and *epagôgê* (inductive reasoning, argument by example, or reasoning involving

[68] Peter Goodrich, *Rhetoric as Jurisprudence: An Introduction to the Politics of Legal Language*, 4 OXFORD J. LEGAL STUD. 88, 97 (1984) (explaining that the forensic topoi was one of a tripartite: deliberative, forensic, panegyric topoi, in reference to the audiences at which the speech was directed; Aristotle used *topoi* to describe specific logical and rhetorical methods specific to a field, with topoi in a legal field typically being called *forensic* topoi).

[69] *See generally* ARISTOTLE, PRIOR ANALYTICS. INTERNET CLASSICS ARCHIVE (A.J. Jenkinson trans., 2009), http://classics.mit.edu/Aristotle/prior.html [https://perma.cc/4NFB-JXJE].

outside information).[70] Aristotle considered the syllogism the most persuasive of all logical reasoning, and arranged syllogisms with two or more *prostasis* (premises). The Aristotelian syllogism included a universal statement as the major premise (P1), followed by a second universal as the minor premise (P2), followed by a conclusion ('therefore,' or ∴):[71]

P1	All men are mortal ∧[72]
P2	Socrates is a man
∴[73]	Socrates is mortal

Comparatively, argument by example invokes inductive reasoning by using specific *paradeigma* (examples) to sustain a conclusion.[74] Example arguments typically required an exhaustive list of several examples (P) within the same grouping to logically prove a conclusion, rather than one example:[75]

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[70] *See generally* Richard D. McKirahan, *Aristotelian Epagoge in Prior Analytics 2. 21 and Posterior Analytics 1. 1*, 21 JOUR. HIST. PHIL. 1 (1983) (describing Aristotle's conception of inductive reasoning and use of epagoge, epagestshai, and epaktikos).

[71] *See* ARISTOTLE, *supra* note 69.

[72] Miguel Palomino, *Formal Logic* 2 (2012), http://maude.sip.ucm.es/~miguelpt/papers/flogic.pdf [https://perma.cc/S238-Y5YL] (noting the symbol "∧" represents "and" in formal logic).

[73] Phillip Kirlin, *Formal Logic Reference* Sheet, http://www.cs.rhodes.edu/~kirlinp/courses/discrete/s13/cheatsheet.pdf [https://perma.cc/2RWC-GFFU] (last visited Sept. 15, 2016) (noting the symbol "∴" represents "therefore" in formal logic).

[74] *See generally* ARISTOTLE, POSTERIOR ANALYTICS, INTERNET CLASSICS ARCHIVE (A.J. Jenkinson, trans., 2009), http://classics.mit.edu/Aristotle/posterior.html [https://perma.cc/4NFB-JXJE].

[75] *See generally* FREDERICK COPLESTON, S.J., HISTORY OF PHILOSOPHY: VOLUME 1: GREECE AND ROME (1993).

P	Socrates is a man and died ∧
P	Plato is a man and died ∧
P	Aristotle is a man and died ∧
P	Cicero is a man and died ⇒[76]
∴	Men are mortal

In an argument by example, the audience evaluates the sufficiency of examples to determine if the conclusion is or is not logically complete.

Litigators and courts utilize a version of syllogistic reasoning and arguments by example to propose or determine legal outcomes.[77] Unlike strict logical proofs, litigators and courts typically use rhetorical syllogistic reasoning, a combination of logic and belief leveraging

[76] A.J. Hildebrand, *Logical statements: summary of definitions, notations, and terminology*, UNIV. ILL. (2014), http://www.math.illinois.edu/~ajh/347.summer14/logic.pdf [https://perma.cc/3H89-HV3T] (noting the symbol "⇒" represents "implies" in formal logic; even in inductive proofs, the conclusion does not completely follow from the premises).

[77] ARISTOTLE, TOPICS, INTERNET CLASSICS ARCHIVE, (W. A. Pickard-Cambridge, trans., 2009), http://classics.mit.edu/Aristotle/topics.mb.txt [https://perma.cc/4NFB-JXJE]. "Whether two things are 'the same' or 'different' . . . may be examined in the light of their inflexions and coordinates and opposites." *Id.* This concept is fairly obvious when an individual reads a judicial opinion, arguments by example most typically involve similarity or difference from case precedent. However, the examples used are real examples, not substitutes for actual data, although the similarity or difference from these examples requires a different mode of reasoning than looking at the facts of the present case, and the case alone.

probabilities to illustrate that premises are more likely than not to occur[78] or use the most persuasive examples.[79]

Commonly, the rhetorical (persuasive) expression of a syllogism takes the form of an *enthumêma* (enthymeme).[80] An enthymeme is a purely persuasive device, shortcutting a full syllogism's logical structure by removing one of the premises and instead requiring the audience to make a logical leap.[81] Enthymemes depend on information believed to be true by the audience, whether logically true or not: *Socrates is a philosopher ⇒Socrates is a good and honest man.*[82] In this enthymeme, the audience would have to believe that philosophers as a group overall are more likely than not to be honest and good in order to believe that Socrates is a good and honest man. Arguments coupling

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[78] Edward H. Madden, *Aristotle's Treatment of Probability and Signs*, 24 PHIL. SCI. 167 (1957). Probability is an important aspect of Aristotle's syllogistic reasoning, especially for rhetorical proofs. In some cases, the premise is less an argument than a maxim, or a generally known concept the audience agrees with, e.g., "man may not patent nature."

[79] *See* ARISTOTLE, *supra* note 77.

[80] *See, e.g.*, Lloyd F. Bitzer, *Aristotle's Enthymeme Revisited*, 45 Q. J. SPEECH 399 (1959) (analyzing the role of the enthymeme in language); Richard L. Lanigan, *Enthymeme: The Rhetorical Species of Aristotle's Syllogism*, 39 SO. SPEECH COMM. JOUR. 207 (1974) (describing the role of the enthymeme as a derivation of the syllogismos); Edward H. Madden, *The Enthymeme: Crossroads of Logic, Rhetoric, and Metaphysics*, 61 PHIL. REV. 368 (1952) (illustrating the connections between Aristotle's works); James H. McBurney, *The Place of the Enthymeme in Rhetorical Theory*, 3: SPEECH MONOGRAPHS 49 (1936) (describing the significance of the enthymeme as a foundation of rhetorical theory).

[81] *Id.*

[82] PATRICIA BIZZELL & BRUCE HERZBERG, THE RHETORICAL TRADITION: READINGS FROM CLASSICAL TIMES TO THE PRESENT 172 (1990).

examples, whether actual (as in case precedent) or manufactured (as in metaphor) with an enthymeme often form the most effective form of persuasion.[83]

Courts have a long history of using analogies and metaphors to make judicial decisions.[84] Analogical reasoning has been used to enhance consistency for cases and courts since the beginning of reasoning based on stare decisis.[85] Analogical reasoning is inferential reasoning, which requires additional outside information to come to a particular conclusion, and analogical reasoning includes both reasoning by analogy and by metaphor.[86]

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[83] *Id*. (reciting what Aristotle said, "The true and the approximately true are apprehended by the same faculty.").

[84] Emily Sherwin, *A Defense of Analogical Reasoning in Law*, 66 U. CHI. L. REV. 1179, 1180 (1999).

[85] Thomas R. Lee, *Stare Decisis in Historical Perspective: From the Founding Era to the Rehnquist Court*, 52 VAND. L. REV. 647, 659–61 (1999) (describing that the evolution of the common law in the early 18th Century necessarily included stare decisis and persuasive precedent to reduce highly inconsistent rulings).

[86] For a more complete description of the use of analogy and precedent in the common law legal system, *see Precedent and Analogy in Legal Reasoning*, STAN. ENCYC. PHIL. (June 20, 2006), http://plato.stanford.edu/entries/legal-reas-prec/ [https://perma.cc/8VDY-UWXP]. Legal reasoning often includes the act of distinguishing between the present case and one of precedent, often using analogy. Analogical reasoning includes use of both analogy and metaphor, although analogy and metaphor individually are somewhat different persuasive vehicles. Analogy in particular is usually something true and decided held in comparison another case similar in nature to the present case, whereas a metaphor is invented by the speaker, a creation. *Compare Analogy and Analogical Reasoning*, STAN. ENCYC. PHILOSOPHY (June 25, 2013), http://plato.stanford.edu/entries/reasoning-analogy/ [https://perma.cc/FV4K-XFLF] *with Aristotle's Rhetoric,* STANFORD ENCYCLOPEDIA OF PHIL., (Feb. 1, 2010), http://plato.stanford.edu/entries/aristotle-rhetoric/ [https://perma.cc/4RBG-Q37N] (providing descriptions of analogy and metaphor, respectively). Please note: Aristotle's concept of metaphor

While some legal scholars have argued that the use of metaphors overall creates a system of unfairness,[87] analogical reasoning still reflects the primary method for judicial analysis.[88] As a result, examining metaphors used in analogical reasoning can help to unveil how courts decide cases, and how metaphor can shape future decisions on related substantive legal questions.[89]

Both syllogism, as deductive reasoning, and analogical reasoning, as inductive reasoning, create the primary structure for *forensic topoi*, but a litigator or court may prefer an enthymeme to more easily communicate a complex idea, rather than a complete logical exploration of the subject matter itself.[90] Aristotle believed *metaphora*

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is used within this article, where use of an enthymeme involving metaphor could also include more modern conceptions of metonomy or synecdoche.

[87] *See supra* note 87, at 1184–85 (describing that Frederick Schauer argues that analogical reasoning is a form of deduction from rules; Richard Posner argues that sometimes law is a form of deduction from rules not fully justified, and courts should engage in straightforward analysis; and Larry Alexander argues that moral reasoning is a superior form of reasoning to analogical reasoning); s*ee generally infra* note 93.

[88] *See* Sherwin, *supra* note 84, at 1181.

[89] *See* Linda L. Berger, *Metaphor and Analogy: The Sun and Moon of Legal Persuasion*, 22 J.L. & POL'Y 147 (2013). Berger argues that metaphor and analogy are the primary means through which we can understand something unknown with our understanding of something else. In short, metaphor and analogy help individuals understand new information. Berger acknowledges that perception and interpretation (fueled by metaphor and analogy) require the classification and grouping of like with like. These frameworks in a legal sense create a structure from which to make legal decisions. *See also* Stephanie A. Gore, *"A Rose by Any Other Name": Judicial Use of Metaphors for New Technologies*, 2003 U. ILL. J. L. TECH. & POL'Y 403.

[90] Cass R. Sunstein, *On Analogical Reasoning*, 106 HARV. L. REV. 741, 782 (1993) (describing that enthymemes are often coupled with analogies to enhance and simplify the analytical process).

(metaphors) transfer characteristics of one object to another and may effectively substitute or support premises,[91] and demonstrate the most persuasive form of enthymeme.[92] Foundational argumentation through syllogism and enthymeme form the *ratio decidendi*,[93] which is then applied to future cases through precedent or analogical reasoning.[94] Analogical reasoning of this type forms the scaffolding of epistemic goals or values, how courts understand the law, through a balance of stability (precedent) and innovation (new interpretations or adaptations of precedent).[95]

When forensic analogical reasoning includes metaphors, it usually is presented first as a premise involving a universally applied rule of law, followed by metaphor.[96]

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[91] *Aristotle's Rhetoric*, STAN. ENCYC. PHIL., (Feb 1, 2010), at § 8.2, http://plato.stanford.edu/entries/aristotle-rhetoric [https://perma.cc/YT2D-YTLM].

[92] *See* Goodrich, *supra* note 71, at 106–07; *see also* ARISTOTLE, POETICS, INTERNET CLASSICS ARCHIVE (S. H. Butcher, trans., 2009), http://classics.mit.edu/Aristotle/poetics.html [https://perma.cc/4NFB-JXJE].

[93] *See* Sunstein, *supra* note 93, at 749. Analogy in the law can be expressed in four steps: a fact pattern has a characteristic/s; another fact pattern differs some but shares some characteristic/s; the law treats (or treated) the original fact pattern in a certain way; if the characteristics of the two fact patterns are the same, the law should treat them the same. *Id.* at 745. This reference illustrates a combination of both syllogism and argument by example.

[94] *Analogy and Analogical Reasoning*, STAN. ENCYC. PHIL. (Jun. 25, 2014), http://plato.stanford.edu/entries/reasoning-analogy/ [https://perma.cc/MXK4-36AU].

[95] Emily Sherwin, *A Defense of Analogical Reasoning in the Law*, 66 U. CHI. L. REV. 1179, 1181–99 (1999) (describing the function of analogy in the law, including criticisms).

[96] *See* BIZZELL & HERZBERG, *supra* note 85, at 235 (explaining that, "Arguments may be raised in four ways— either by directly attacking your opponent's own statement, or by putting forward another statement like it, or by putting forward a statement contrary to it, or by quoting

The metaphor used illustrates a situation commonly understood to meet or not meet a legal standard developed through statute or precedent:

> P1 Individuals may not patent discoveries but may patent inventions ⇒ Individuals may not patent a leaf, which is cut from a tree ⇔[97]
> P2 This individual's invention is the same as patenting a leaf, cut from a tree ⇒
> ∴ This individual may not patent her invention

In reality, no rational person would really attempt to patent "a leaf, cut from a tree" as a whole, yet this metaphor identifies a lens through which other potential inventions should be evaluated, what Aristotle would consider a "universal" premise.[98] Here, using analogical reasoning via metaphor (enthymeme) presents a descriptive reference point to evaluate the similarity or difference of a particular discovery or invention and its attendant circumstances.

In standard analogy to precedent, or arguments by example, litigators and courts analogically compare and

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previous decisions," and that "Universal" in this context is used within the universality of a common system, such as the common law or regulatory system within a particular jurisdiction).

[97] *Logic Symbols*, RAPIDTABLES (2016), http://www.rapidtables.com/math/symbols/Logic_Symbols.htm [https://perma.cc/YH5Q-3CL4] (explaining that, the symbol "⇔" establishes material equivalence between the subject and the object. For this logical proof, the metaphor and the present case are the same).

[98] Although "universal" is a term used in relation to syllogistic reasoning, Aristotle classified individual premises as universal or singular in nature, so it is instruction with relation to inductive reasoning and the enthymeme as well. Universals are not specific to an individual situation, but are applicable across situations. *See generally* Kelley L. Ross, *Aristotelian Syllogisms*, THE PROCEEDINGS OF THE FRIESIAN SCHOOL, FOURTH SERIES (2002), http://www.friesian.com/aristotl.htm [https://perma.cc/AK3B-Q8WP].

contrast actual legal fact patterns to the immediate case in order to establish a standard of practice.[99] Analogical reasoning with an argument by example differs significantly from analogical reasoning with a metaphor because the examples used are generally highly specific and evidence historical, factual circumstances with attendant circumstances (and more detailed information) rather than pure invention.[100] In legal reasoning, arguments by example typically reference legal precedent (binding or persuasive):

> P Extracted chemicals from an Amazon plant are not patentable ∧
> P Condensed lithium is not patentable ∧
> P Human adrenaline is not patentable ∧
> P Combining a naturally occurring bacteria and plant is not patentable ⇒
> ∴ This invention is most similar to examples above and is therefore not patentable.

Examples create a sense of inevitability, even though they require cognitive juxtaposition and a logical jump between historical examples and the present case.[101] To further substantiate these examples, litigators and courts explain the aspects of similarity between the examples and the present case, comparing or contrasting circumstances or attributes to illustrate the degree of similarity.[102] In some cases, parties

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[99] Arguments by example are a different classification than metaphors, although they are both part of the same analogical reasoning arm, both relying on inductive, rather than deductive reasoning.

[100] *See Aristotle's Rhetoric*, *supra* note 94.

[101] Courts must examine cases side by side to compare and contrast attributes, then reason that case precedent or hypothetical examples and the present case are similar or different, meriting or not meriting the same legal conclusion.

[102] *See* O'Donnell, *supra* note 15, at 4 (explaining that this similarity is often used to analogize to precedent, with a foundation of the French

may include a large number of examples to further establish a sense of inevitability for their respective audiences.[103]

B. Examining Metaphors in Myriad

In patent law, like many other fields of law, metaphors are often leveraged to explain complex concepts, especially to courts without specialization in highly complex scientific and technical subject matter.[104] If courts analyze a case using deductive, rather than inductive reasoning, what may seem to be a straightforward application of 101 could require highly specialized analyses of specific scientific or technological facts and details to determine eligibility.[105] Due to the complex nature of the science under examination, a court or party's choice and heavy adoption of a particular analogy or metaphor can uncover hidden values and

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and English royal courts who believed that like cases should be decided alike, a John Rawls-style equity, or "formal justice.").

[103] A "pile on" of examples in patent law may assist in persuading a court or jury, especially where objective understanding of the invention itself is questionable.

[104] This is a legitimate step in many ways, especially because most justices and juries do not possess highly scientific backgrounds, and most scientific fields are highly specialized. In order to understand how a scientific invention functions, parties and courts employ metaphor to illustrate what the invention is or isn't, as well as how the science meets basic requirements of novelty, utility, non-obviousness, and subject matter eligibility.

[105] *See generally* Jonathan J. Darrow, *Secondary Considerations: A Structured Framework for Patent Analysis*, 74 ALB. L. REV. 47 (2011). Unfortunately, the lack of an effective framework often requires courts to consider secondary considerations, or attendant circumstances of the invention. As such, courts already are accustomed to reasoning according to external factors rather than a structured, analytical process, often relying on a "chain of inferences" to make a decision. Moving jurisprudence towards a fact-based reasoning likely requires educational background and specialization of judges to review highly complex cases.

understanding of the law applied to the subject matter discussed, an attachment of values or circumstances surrounding the analogy or metaphor to the present case.[106]

In the *Myriad* line of cases, courts examined whether biological sequence segments met known nature exceptions to 101 (abstract idea, natural phenomenon, or law of nature) by comparing and contrasting isolated DNA segments with metaphors and analogy to case precedent.[107] In order to uncover which analogies or metaphors used in *Myriad* might suggest eligible legal solutions to protect otherwise patent-ineligible biological sequences, this Author used four analytical steps to review the *Myriad* structure: 1) a contextual inquiry of word frequency and usage, 2) analogy and metaphor identification, 3) metaphor categorization and labeling, and 4) results analysis.

Contextual inquiry leveraged a combination of qualitative and quantitative methodologies to investigate the use of analogy and metaphor, first establishing context by counting word usage (by individual word count and key phrases) in the District Court, Federal Circuit, and Supreme Court documents to determine overall linguistic context.

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[106] Robin Feldman, *Whose Body Is It Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law*, 63 STAN. L. REV. 1377, 1386 (2011) (explain that using specific analogies imbues the subject matter with certain values and understanding, and that at times this can be misleading when metaphors from the physical sciences, for example, are applied to the biological sciences, which include a different legal understanding of patent law).

[107] *See generally* Dana Milbank, *At Supreme Court, cookies and baseball bats*, WASHINGTON POST (Apr. 15, 2013), http://www.washingtonpost.com/opinions/dana-milbank-justices-rely-on-analogies-to-decide-ownership-of-genetic-material/2013/04/15/1b758e90-a611-11e2-a8e2-5b98cb59187f_story.html [https://perma.cc/7FE4-T7J8]; *Patentability of Isolated DNA: A Myriad of Analogies*, THE IPKAT BLOG, (Sept. 4, 2012), http://ipkitten.blogspot.com/2012/09/patentability-of-isolated-dna-myriad-of.html [https://perma.cc/S743-5P68].

This Author surveyed all court documents from the central parties and the courts, except *amicus briefs* (*see* Appendix).[108]

Next, arguments were identified as syllogism, enthymeme, or argument by example by identifying and hand-coding arguments and references in the full *Myriad* case document corpus. This grouping helped to identify whether courts primarily used syllogisms or analogical reasoning and helped to identify the origins of analogy and metaphor use throughout *Myriad,* revealing the most successful metaphors used in relation to isolated DNA.

After metaphors were identified within each argument, the Author grouped metaphors by reasoning type, metaphorical genus (grouping), metaphor species (name), person or party uttering the analogy, and frequency of metaphor usage by court. After identification and categorization, these metaphors were analyzed to determine the three most successful metaphors used. All metaphors were evaluated in complete analogical argumentation structure, line-by-line, and summarized to determine which values, probabilities, or inductive reasoning surrounded the topic of patenting isolated DNA. Analogical usage relating to isolated DNA should identify the most appropriate legal instruments that can adequately protect patent-ineligible biological sequences more broadly.

[108] *See infra* Appendix. The total corpus included 40 documents 12,400 words, and 344 metaphors analyzed. Words were analyzed with an auto-analysis computerized tool due to the large corpus size. Amicus briefs were removed from the corpus, as many were purely explanatory or focused on questions of public policy. Metaphors were hand-identified, hand-coded, and hand-summarized. This analysis focused on identifying court openness to alternative legal instruments, and as-such, amicus briefs would not reflect this concept.

III. ANALYSIS RESULTS

The use of analogical reasoning in the law offers an opportunity to understand how courts interpret the facts of a case. Metaphors and arguments by example used in *Myriad* not only illustrate how courts may decide patent cases involving the nature exception, but may also introduce potential means of understanding alternative, acceptable legal frameworks applying to biological sequences classified as patent-ineligible, natural discoveries.

A. Overall Context

The *Myriad* cases focused primarily on DNA and patent language (*see* Figure 1). While courts discussed DNA in roughly the same proportion to other types of subject matter, three exceptions did exist. The District Court used the most references to human beings of any court (including language around patients, clients, and public policy), the Federal Circuit described more details of the DNA itself, and the Supreme Court used dramatically more "nature" and "discovery" language (*see* Figure 2).

One of the most common phrases for the District Court included "the common heritage of humanity," a phrase used heavily during the Human Genome Project (HGP) to advocate for HGP database openness.[109] The Federal Circuit, in comparison, focused on the patent itself and the economic implications of patenting, "expectations of the investing community." The Supreme Court, comparatively, focused on the information encoded within DNA base pairs rather than its function or use, "information encoded in the BRCA gene," most frequently.

[109] David B. Resnik, *The Human Genome: Common Resource But Not Common Heritage*, 5 ETHICS FOR LIFE SCIENTISTS 197 (Michiel Korthals & Robert J. Bogers eds., 2005).

The prevalence of language used in these courts seem to predict case holdings. The District Court, adopting a humanist perspective, focused most on the impact to human beings, for example lack of additional choices for BRCA1, BRCA 2, and BART testing, and an inherent unpatentability of products derived from a human being. The Federal Circuit, with the most scientific experience, focused on understanding the technology itself and the relationship between patents and the economy. By focusing on the technology and the economy, by extension, the Federal Circuit necessarily also focused on the technology's utility and function to determine whether the United States should uphold a monopoly for inventions with limited utility involving naturally derived biological material. While the Federal Circuit investigated patent eligibility under 101, the Supreme Court focused the most on the nature exception itself, narrowing its inquiry and distinguishing between discovering a product in nature with utility versus a novel human contribution, which resulted in the "split the difference" verdict of patent protection for cDNA (requiring heavier human involvement) and isolated DNA, with less human involvement and much closer status to wild-type DNA.

B. Analogical Reasoning and Metaphor Use

Courts used analogical reasoning in each decision, adopting enthymemes to establish a point of view. The District Court balanced enthymemes and arguments by example the most, likely because of the court's desire to exhaust binding and persuasive case precedent and exhibit due diligence in examining the case at hand. The Federal Circuit and the Supreme Court used enthymemes the most, at 70% and 78%, respectively (*see* Figure 3).[110] The most

[110] *See infra* Figure 3. The Federal Circuit and Supreme Court's heavy use of enthymeme illustrates a desire to innovate on *ratio decidendi* and

staggering revelation of this rhetorical analysis was the significant departure of courts, even the District Court, from full logical evaluation of the case-at-hand to using syllogism.[111] In fact, all three courts only used deductive reasoning six times in comparison to 337 examples of analogical reasoning.[112]

By analogy, courts compared and contrasted wild-type DNA to isolated DNA the most, at 20–27% across courts, legitimately investigating whether isolated DNA had enough human involvement and transformation from its wild-type form to merit patent eligibility (*see* Figure 4). Outside analogizing between isolated DNA and wild-type DNA, courts used biomass metaphors at 25% and other physical matter at 25%.

C. Biomass Metaphors—Plant, Organs, Bacteria

The Supreme Court focused most on plants, bacteria, and organs, all initially described by the Federal Circuit (*see* Figure 5). The most common enthymemes used included patenting a kidney, a leaf from a tree, a wild plant in the Amazon, and a baseball bat formed from a tree. Courts described DNA isolation—segmenting DNA, removing the DNA from its intra-cellular environment, and changing the terminal end chemical sequences—as a more technically

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do so not through traditional logic or case precedent, but through analogy in the *forensic topoi*. This result seems rational, given that higher courts have considerably more latitude to innovate or characterize precedent through new perspectives.

[111] *Id.*

[112] Although it is understood that analogical reasoning is used in courts, the degree to which it is used in this particular case is staggering and gives pause to those who might advocate for holistic logical legal analysis. The large percentage of enthymemes illustrates a departure from true precedent towards heavy reliance on metaphor.

advanced version of removing a portion of something that already exists. The kidney is like natural DNA, removed from the body, yet retaining its original status as a kidney. The leaf still remains a leaf and has inherent chemical properties, though a human severed the leaf from a tree or a wild plant in the Amazon. Regardless of how hard it is to sever or remove natural material, it remains natural. In contrast, a baseball bat may have started as a tree, but it bears little resemblance now, as humans have made many choices about its shape, structure, soundness, and utility for playing baseball.

Argument by example included analogy to bacteria from *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[113] and *Diamond v. Chakrabarty*,[114] the two Supreme Court nature-exception precedential cases, both of which relate to bacteria rather than biological sequences. Courts used *Funk Bros.* and *Chakrabarty* bacteria to evaluate similarity and dissimilarity: whether isolated DNA was more similar to combined natural bacteria found in the soil (patent-ineligible) or more similar to oil-consuming, man-made bacteria not occurring in nature (patent-eligible).

D. Matter Metaphors

The most common, matter-metaphors involving elements included gold, found in a streambed and separated; elemental lithium, not occurring naturally but with inherent natural properties; mining versus carving marble; cleaning a raw diamond; and producing ductile uranium, vanadium, and tungsten. Panning for gold represented the longest running metaphor through all courts, starting in the original complaint through to the Supreme Court. This metaphor described finding gold when panning, explaining that if a

[113] 333 U.S. 127 (1948).

[114] 447 U.S. 303 (1980).

person returns the gold to the streambed, it reintegrates. Without more human involvement (such as creating a new way of making gold into jewelry), gold is not patent-eligible simply because removing it from the streambed revealed its value. Similarly, though humans must render a pure lithium element, the useful aspects of lithium exist inherently in the element. In this metaphor, humans do not create utility, a human uncovers the inherent utility. The court then extended the "inherent utility" argument (inherent utility results in patent-ineligible discoveries) to minerals and elements like marble, diamonds, and inherently ductile uranium, vanadium, and tungsten to describe their inherent value despite human involvement.

The elucidation of highly varied patent-ineligible and eligible products demonstrates the jurisprudential challenge of fully examining eligibility of a scientific process, such as isolated or cDNA. By analyzing how *Myriad* courts determined patent eligibility, perhaps analysis outcomes can help to inform future legal protection options for biological sequences.

IV. ALTERNATIVE LEGAL PROTECTION FOR BIOLOGICAL SEQUENCES

Although the Supreme Court in *Myriad* provided some direction on the patent eligibility of genetic material, biotechnology companies still face practical decisions regarding appropriate legal strategy, which could include copyright of compilations (thin copyright), database protection, or trade secret protection.

A. Copyright Protection for Compilations

The United States Constitution sets the context for patent and copyright protection: "to promote the progress of science and useful Arts, by securing for limited times to authors and inventors the exclusive right to their writings

and discoveries."[115] Though copyright and patent rights have never been declared mutually exclusive,[116] in *Baker v. Seldon*,[117] courts found that patent law protects the idea, while copyright law protects the expression of that idea. Title 17 of the United States Code adds additional detail, covering "original works of authorship . . . perceived, reproduced . . . with the aid of a machine or device."[118] Section 102 goes on to enumerate eligible works of authorship and including some limiting language:

> In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.[119]

While on its face, § 102 does not appear to cover scientific subject matter; § 103, Compilations and Derivative Work, does provide additional protection:

> (a) The subject matter of copyright as specified by section 102 includes compilations and derivative works . . . . (b) The copyright in a compilation or derivative work extends only to the material contributed by the author of such work, as distinguished from preexisting material employed in

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[115] U.S. CONST. art. I, § 8, cl. 8.

[116] Viva R. Moffat, *Mutant Copyrights and Backdoor Patents: The Problem of Overlapping Intellectual Property Protection*, 19 BERKELEY TECH. L.J. 1473, 1497–1503 (2004).

[117] 101 U.S. 99 (1879), *superseded by statute as recognized in* Close to my Heart, Inc. v. Enthusiast Media LLC, 508 F. Supp. 2d 963 (D. Utah 2007).

[118] 17 U.S.C. § 102 (2012).

[119] *Id*.

> the work, and does not imply any exclusive right in the preexisting material.[120]

Compilations, according to common law application of § 103, have expanded to include compilations of facts,[121] such as a plat map of land parcels,[122] a compilation of phone numbers in a phone book,[123] a used vehicle valuation database,[124] compilations of judicial opinions on a CD-ROM,[125] and an automobile parts catalogue.[126]

In a compilation, protection may be extended to the selection, coordination, or arrangement in the work as a whole, if it demonstrates some level of originality.[127] Alternatively, some data sets of unoriginal elements cannot be compiled because they dictate their own proper arrangement.[128] When copyright protection is available for factual compilations, it is thin because authors typically do

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[120] 17 U.S.C. § 103.

[121] *See generally*, Gerard J. Lewis, Jr., *Copyright Protection for Purely Factual Compilations Under Feist Publications, Inc. v. Rural Telephone Service Co.: How Does Feist Protect Electronic Data Bases of Facts?* 8 SANTA CLARA HIGH TECH. L.J. 169 (1992).

[122] Rockford Map Publishers, Inc. v. Directory Serv. Co. of Colorado, Inc., 768 F.2d 145, 148–49 (7th Cir. 1985).

[123] Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., Inc., 499 U.S. 340, 363–64 (1991).

[124] CCC Info. Serv., Inc. v. Maclean Hunter Mkt. Reports, Inc., 44 F.3d 61, 67, 73 (2d Cir. 1994).

[125] Matthew Bender & Co. v. West Publ'g Co., 158 F.3d 693, 702 (2d Cir. 1998).

[126] ATC Distrib. Grp., Inc. v. Whatever It Takes Transmission & Parts, Inc., 402 F.3d 700, 710 (6th Cir. 2005).

[127] Deborah F. Buckman, Annotation, *Copyright Protection of Computer Programs*, 180 A.L.R. Fed. 1 (2002).

[128] *Id*.

not contribute as much original matter to a compilation as they might to an original work.[129] Demonstrating infringement, as a result, is more difficult,[130] as others may legitimately use the contents of factual works but may not infringe the selection or arrangement of the compilation of these facts.[131] Copyright infringement analysis still requires a comparison between the original and the copy to establish substantial similarity between protected selection and arrangement,[132] rather than non-protectable content.[133] Some courts require virtually identical status between the plaintiff's work and the defendant's work to prove infringement.[134]

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[129] David E. Shipley, *Thin But Not Anorexic: Copyright Protection for Compilations and Other Fact Works*, 15 J. INTELL. PROP. L. 91, 130–31 (2007).

[130] *See generally* Lewis, *supra* note 121. While *Feist Publ'ns, Inc.* required only a "minimum spark" of originality, proving infringement requires proving infringement of the minimum spark rather than copying of facts or non-protectable elements in a compilation.

[131] Raymond T. Nimmer, 1 INFO. L. § 3:16 (2006).

[132] Substantial similarity analysis compares and contrasts aspects of the work to determine how much content the defendant has copied and whether the content copied is protectable by law. For compilations, much of what could be copied is not protectable (facts being part of the public domain).

[133] *See* Moffat, *supra* note 116.

[134] *See* ATC Distrib. Grp., Inc. v. Whatever It Takes Transmission & Parts, Inc., 402 F.3d 700, 705 (6th Cir. 2005); *see also* Charlotte A. Tschider, *Automating Music Similarity in "Sound-Alike" Music Cases*, 25 N.Y. ST. B. ASS'N. ENT., ARTS & SPORTS L.J. 60, 60–63 (2014) (evaluating substantial similarity analysis for the music genre in specific circuits); John A. Odozynski, *Infringement of Compilation Copyright after Feist*, 17 U. Dayton L. Rev. 457, 496–97 (1992) (proposing an approach for evaluating compilation substantial similarity); Howard Root, *Copyright Infringement of Computer Programs: A Modification of the Substantial Similarity Test*, 68 MINN. L. REV. 1264 (1984) (orienting readers to substantial similarity analysis

The *Feist* decision dispensed with the "sweat of the brow" or contribution rule for copyright eligibility and replaced it with the "minimum spark" test.[135] This test requires some level of originality in the selection and arrangement of the non-protectable content, leaving less original, yet heavy-investment compilations without copyright protection.[136]

While the legislative history of the 1976 Copyright Act illustrates Congress's intent to keep the phrase "original works of authorship" open-ended and provides protection for compilations,[137] it is unclear whether Congress contemplated the protection of biological sequences through the copyright legal scheme.[138] In 1987, the U.S. Copyright Office stated it would refuse copyright registration for DNA

differences between computer programs and other protectable expression genres). It is unclear, given existing inconsistencies and challenges in substantial similarity analysis, how courts might interpret copyright infringement of biological sequences generically, in particular, the degree of similarity needed for a genetic "compilation" to effectively merit legal recovery.

[135] *See* Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., Inc., 499 U.S. 340, 359–60 (1991).

[136] *See generally,* David E. Rigney, *What Constitutes a "Compilation" Subject to Copyright Protection—Modern Cases*, Annotation, 88 A.L.R. Fed. 151 (1988) (describing the conditions for achieving enforceable copyright for compilations).

[137] Irving Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 191, 201 (1982) (contemplating the potential challenges of protecting biological data and proposing the possibility of protecting DNA via human-compiled combinations of individual DNA fragment or plastid).

[138] *See* Howard G. Zaharoff, *Advising a Massachusetts Business*, § 2-1 (2011) (describing a history of scholars proposing copyright protection for recombinant DNA, yet acknowledging no general indication of intent to protect recombinant DNA via copyright).

and has not revisited the question.[139] The similarity between biological sequences and computer software code is certainly compelling: Both fields require levels of abstraction, specialized skill, and specific machinery to read the information presented.[140] However, though the public domain limits enforcement of copyright for coding language per se, software developers contribute significantly through selection and arrangement within unprotected coding languages.[141] Biotechnologists may contribute

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[139] Keith Aoki, *Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain Part II*, 18 COLUM. J.L. & ARTS 191, 203–09 (1994) (Describing that, in 1987, Walter Gilbert attempted to assert copyright interest in genetic information, prompting a negative response from the scientific community); *see also*, Rochelle K. Seide & Frank A. Smith, *Intellectual Property Protection and Biotechnology*, 67 N.Y. ST. B.J. 52, 58 (1995).

[140] Donna Smith, Comment, *Copyright Protection for the Intellectual Property Rights to Recombinant Deoxyribonucleic Acid: A Proposal*, 19 ST. MARY'S L.J. 1083, 1108–09 (1988).

[141] Christopher M. Holman, *Copyright for Engineered DNA: An Idea Whose Time Has Come?*, 113 W. VA. L. REV. 699, 714–15 (2011); *see, e.g.*, Dennis S. Karjala, *Protecting Innovation in Computer Software, Biotechnology, and Nanotechnology*, 16 VA. J.L. & TECH. 42 (2011) (comparing biotechnology to software and recognizing the challenges of patenting certain types of DNA sequences); Andrew W. Torrance, *DNA Copyright*, 46 VAL. U. L. REV. 1 (2011) (describing DNA language and concepts, comparing DNA to other copyrightable areas of knowledge, and deeply exploring the application of copyright fundamentals to DNA molecules); Stephen R. Wilson, *Copyright Protection for DNA Sequences: Can the Biotech Industry Harmonize Science with Song?*, 44 JURIMETRICS J. 409 (2004) (describing the similarities between DNA and music from a sequencing perspective and suggesting copyright protection as a potential legal solution); M. Scott McBride, *Bioinformatics and Intellectual Property Protection*, 17 BERKELEY TECH. L.J. 1331 (2002) (evaluating patent, copyright, and trade secret as potential legal protection for DNA, RNA, protein sequences, and biological databases); Irving Kayton, *Copyright in Living Genetically Engineered Works,* 50 Geo. Wash. L. Rev. 191 (1982) (introducing the possibility of copyright protection for

comparatively less to the molecular code of, for example, isolated DNA: selecting where to terminate and choosing specific molecular groups to reside on either end of the nucleotide chain.[142] If, however, biotechnologists can effectively arrange biological sequences to meet the minimum spark of creativity for compilation,[143] biotechnology companies could enjoy lengthy copyright protection.[144]

B. Alternate Protection through a Database Directive (Copyright Exception)

In order to protect collections of compiled information, the European Union created the 1996 Database Directive[145] as alternate protection for databases not covered by traditional copyright protection, though this directive is

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genetically engineered works and suggesting the possibility of protection via multiple legal avenues including patent, trade secret, and copyright as well as potential drawbacks given the length of copyright protection); *see also* Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J.L. SCI. & TECH. 629 (2010) (investigating the possibility of copyright application to synthetic DNA, describing the possibility of open innovation, and noting previous authors who have addressed this subject); James G. Silva, *Copyright Protection of Biotechnology Works: Into the Dustbin of History?* 2000 B.C. INTELL. PROP. & TECH. F. 12801 (2000) (describing in part, the possibility of copyright compilation as an avenue for biotechnology copyright protection and noting scholars investigating copyright and biotechnology in the 1980s and 1990s).

[142] *See supra* Part I.A.

[143] Ray K. Harris & Susan Stone Rosenfield, *Human Genetic Sampling: Ethical, Legal, and Social Considerations, Copyright Protection for Genetic Databases*, 45 JURIMETRICS J. 225, 239–50 (2005).

[144] *Compare* Aoki, *supra* note 139, at 198–201 *with* McBride, *supra* note 141, at 1363–64.

[145] Parl. Eur. Doc. and Council DIRECTIVE 96/9, 1996 (EC).

not harmonized internationally.[146] Scholars have identified the use of these databases as an alternative practice for bioinformatics databases, maximizing the value of analytic tools and information management schemes, and associated licensing.[147] The protection for database contents provides a cause of action when others extract or utilize the whole or a substantial part of these contents without permission. Some best practices for open data include machine-readable licenses, often using a data mark and metadata for use with databases.[148] This ensures that publicly available information is not subsequently privatized.[149]

While two United States House of Representatives resolutions have previously been raised, the United States has not yet determined whether database protection should be available for the United States.[150] While the World Intellectual Property Office (WIPO) delegates have also

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[146] Julie D. Cromer, *It's Hard to Find a Good Pair of Genes: So Why Make Them Free for the Taking?*, 76 UMKC L. REV. 505, 517–18 (2007).

[147] Dennis Fernandez & Mary Chow, *Intellectual Property Strategy in Bioinformatics and Biochips*, 19 SANTA CLARA COMP. & HIGH TECH. L.J. 491, 497 (2003).

[148] Alex Ball, *How to License Research Data*, DIGITAL CURATION CENTER (July 17, 2014), http://www.dcc.ac.uk/resources/how-guides/license-research-data [https://perma.cc/KA27-8JDM].

[149] Andrew Clearwater, *The New Ontologies: The Effect of Copyright Protection on Public Scientific Data Sharing Using Semantic Web Ontologies*, 10 J. MARSHALL REV. INTELL. PROP. L. 182, 202 (2010).

[150] Edward J. Baba, *From Conflict to Confluence: Protection of Databases Containing Genetic Information*, 30 SYRACUSE J. INT'L. L. & COM. 121, 143–46 (2003); U.S. COPYRIGHT OFFICE, REPORT ON LEGAL PROTECTION FOR DATABASES, 50–52 (Aug. 1997) [hereinafter USCO], http://www.copyright.gov/reports/db4.pdf [https://perma.cc/H6DF-53VG]. Please note: the U.S. Copyright Office has not issued another report on database protection since 1997, illustrating that database protection has not been a recent policy focus.

discussed database protection, the United States did not establish a position on it, tabling the database treaty.[151] While some scholars have argued database protection is a form of unfair competition, others have proposed protection of databases under copyright law.[152] Although many of these discussions fast-followed the *Feist* decision in 1991 and the EU passage of the Database Protection Directive in 1996, perhaps the potential for alternative legal protection for stored biological sequences could reignite policy discussions on the topic.[153]

The complexity of modern science demands larger and more comprehensive data sets in genomic databases, and many gene banks have shut down for lack of funds. Private databases, by comparison, are "well maintained and annotated,"[154] and specific database legislation would better incentivize investment in quality gene banks.[155]

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[151] *See* Baba, *supra* note 150, at 146.

[152] *See* USCO, *supra* note 150, at 89–90; Chana Rungrojtanakul, *Legal Protection of Sui Generis Databases* (2005) (theses, Golden Gate University School of Law), http://digitalcommons.law.ggu.edu/cgi/viewcontent.cgi?article=1015&context=theses.

[153] *See generally* Baba, *supra* note 150 (describing the *Feist* decision in 1991, the attempt at a WIPO treaty in 1996, and the EU Database Protection Directive passage in 1996). It should be noted that databases may also be protected via trade secret. *See generally* Sharon K. Sandeen, *A Contract by Any Other Name is Still a Contract: Examining the Effectiveness of Trade Secret Clauses to Protect Databases*, 45 IDEA 119 (2005) (describing the intersection of database protection and trade secret by way of contractual requirement); Chana Rungrojtanakul, *Legal Protection of Sui Generis Databases* (2005) (unpublished thesis, Golden Gate University School of Law), http://digitalcommons.law.ggu.edu/cgi/viewcontent.cgi?article=1015&context=theses [https://perma.cc/WJX5-B6ZB].

[154] Amol Pachnanda, *Scientific Databases Should Be Protected under a Sui Generis Regime*, 51 BUFF. L. REV. 219, 234–35 (2003).

[155] *Id.* at 236.

Metaphors used in *Myriad*, especially analogizing to wild-type DNA and DNA "sequences," as well as the practical implications of storing DNA, may substantiate the use of thin copyright for biological sequences. As long as individuals provide some spark of originality in relation to the arrangement of DNA databases and DNA collections, protection may be available. In line with software code compilations, DNA code could effectively be stored and protected as a whole. Even if copyright protection may not be available, Congress could reconsider specialized database protection for data requiring significant investment without the limits of thin copyright.

C. Application to Trade Secret

Trade secret law combines aspects of intellectual property law with tort recovery.[156] The Conference of Commissioners of Uniform State Laws initially drafted the Uniform Trade Secrets Act (UTSA) to clarify the common law tort of trade secret misappropriation and create a consistent framework for all states.[157] Trade secrets apply to information including: formulas, patterns, compilations, programs, devices, methods, techniques, or processes that derive economic value from not being known and are subject to reasonable security measures for secrecy.[158] Trade secrets derive their status from state law, loosely grouped with intellectual property rights, but the secrecy required to establish the existence of a trade secret restricts

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[156] John Gladstone Mills III, Donald Cress Reiley III, Robert Clare Highley, & Peter D. Rosenberg, 1 PAT. L. FUNDAMENTALS § 4:3 (2d ed. 2014).

[157] VICTOR D. LÓPEZ, INTELLECTUAL PROPERTY LAW: A PRACTICAL GUIDE TO COPYRIGHTS, PATENTS, TRADEMARKS, AND TRADE SECRETS 89 (2011).

[158] 18 U.S.C. § 1905 (2012).

dissemination may prove incompatible for certain biological sequence uses.[159]

Under the Uniform Trade Secret Act (UTSA), a trade secret exists only for as long as it remains a secret and only applies to current confidential information.[160] This information must be kept confidential to the owner and others who have agreed (via contract or a non-disclosure agreement) to keep the information confidential.[161] Typically, the more employees in the organization who know the information, the less likely it is a trade secret, and it must be difficult for competitors to acquire or duplicate the trade secret independently without resorting to wrongful conduct[162] or requiring a very high price to produce.[163] Furthermore, the UTSA also requires that an individual

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[159] *See* Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 352 (2008); *see generally* Andrew Beckerman-Rodau, *The Choice between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 397–98 (2002) (describing the relative legal and business considerations for selecting patent protection or trade secret protection). Trade secrets derive a beneficial relationship from their classification of IP rights, including courts considering specific trade secret legal requirements, such as secrecy, rather than more fluid pseudo-contract conceptions under contract law.

[160] Louis Altman & Malla Pollack, 3 CALLMANN ON UNFAIR COMPETITION, TRADEMARKS & MONOPOLIES § 14:27 (4th ed. 2013).

[161] *Id*.

[162] John M. Callagy & Richard E. Donovan, 9 BUS. & COM. LITIG. FED. CTS. § 121:14 (4th ed. 2016).

[163] Michelle L. Evans, *Proof of Facts to Establish Information as Trade Secret Under Restatement of Torts*, 134 AM. JUR. 3D 321 (2013). The purpose of trade secrets is to protect organizational investments in information or capabilities to keep them competitive. If the information or capabilities are in the public domain, not important enough to effectively secure them, or identifiable simply by reverse engineering something available in the public, the information or capability is not likely a trade secret.

cannot readily ascertain the contents of the trade secret.[164] For some biological sequences, another person could reverse engineer the sequence via standard, reasonably available lab equipment.[165] These bars to trade secret recovery could make trade secret protection a less favorable option (in some cases) for biological sequences.

Unfair competition laws, including the UTSA, levy heavy penalties for disclosure of a trade secret. If employees violate trade secret protection by disclosing confidential information employees must keep confidential, they can be liable not only under UTSA civil penalties and breach of contract but also potential criminal charges under the Economic Espionage Act of 1996 if they disclose to a foreign state or entity.[166]

Trade secret law provides many advantages for organizations. For one, trade secret statutes protect organizations indefinitely, assuming an entity and its employees can maintain secrecy.[167] While patents tend to be easier to file and can generate revenue through licensing

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[164] Sharon K. Sandeen, *The Evolution of Trade Secret Law and Why Courts Commit Error When They Do Not Follow the Uniform Trade Secrets* Act, 33 HAMLINE L. REV. 493, 523-24 (2010).

[165] *Id*. Isolated DNA and cDNA use as a diagnostic tool was specifically related to its sequence and utility in identifying a matching DNA sequence. Intrinsically, the *Myriad* example cannot be made easily undiscoverable or unknowable. However, other biological sequences may fare better based on expected use.

[166] 18 U.S.C. § 1831 (2012). The Economic Espionage Act levies heavy penalties on foreign corporate espionage, including a five million dollar fine and fifteen years in prison for an individual and a minimum $10 million fine (or three times the value of the trade secret).

[167] Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 383–84 (2002).

schemes,[168] trade secrets work well for organizations that do not prefer to license their inventions and instead aim to establish long-term industry monopoly through private development.[169] For patent-ineligible biological sequences, trade secrets may provide a viable option, so long as sequences cannot be reverse-engineered and organizations can limit access, and adequately secure the sequence itself.[170]

Metaphors from *Myriad*, including typical "sweat of the brow" discovery, illustrate a strong possibility for trade secret protection. Gold, uranium, and Amazonian plants, for example, all represent one concept: significant investment to discover and subsequent market value. Similar to trade secrets, the investment required to independently discover a rare Amazonian plant, as well as competitor organizations keeping the extract a "secret ingredient" in a vitamin supplement, seems most appropriate for designation as a trade secret. Similarly, discovery of genetic diseases and subsequent isolation of genes requires substantial investment, yet provides tremendous market potential for biotechnology companies.

Trade secrets also seem most preferred by genetic research participants. Conley, in particular, surveyed 57 participants "banking" their biological data, and overwhelmingly, the participants recommend very similar

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[168] Mimi C. Goller*, Is a Padlock Better Than a Patent? Trade Secrets v. Patents*, 71 WIS. LAW. 20, 22 (1998).

[169] *See* Andrew A. Schwartz, *The Corporate Preference for Trade Secret*, 74 OHIO ST. L.J. 623, 631 (2013).

[170] Trade secret protection may prove ineffective for many biological sequence uses, as by definition, access to trade secrets likely would be limited. For some businesses using isolated DNA as a core part of operations (i.e. genetic testing facilities), knowledge of the sequence would likely be required for a fairly large population of business personnel.

protection for traditional trade secrets, not only for corporate protection, but for personal privacy, too.[171] Trade secret protection for genetic information mirrors public concerns about the security, handling, and use of the public's most personal data.[172] Myriad Genetics has recently embraced this strategy as well, seeking financial benefits from databases containing genetic data and associated health outcomes.[173]

Alternatively, trade secrets may not work effectively in all environments. Many biotechnology companies have formed either through a university start-up or acquired rights from universities through technology transfer under the Bayh–Dole Act.[174] University researchers, in stark contrast to corporate researchers, most often operate in an open environment, where publishing is desirable and public disclosure is necessary.[175] If a university researcher shares the details of an isolated gene sequence, its associated properties, and a method for identification, this information would be ineligible for trade secret protection, unless UTSA updates included exceptions for open research purposes.[176]

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[171] John M. Conley et al., *A Trade Secret Model for Genomic Biobanking*, 40 J. L. MED. & ETHICS 612, 614 (2012).

[172] *Id.* at 619.

[173] John M. Conley, Robert Cook-Deegan, & Gabriel Lázaro-Muñoz, *Myriad after Myriad: The Proprietary Data Dilemma*, 15 N.C. J. L. & TECH. 597, 616– 19 (2014) (analyzing Myriad Genetics' new approach to protecting its data via proprietary databases and finding potential protection under the Uniform Trade Secrets Act, assuming such proprietary databases cannot be independently created).

[174] *See* Liza Vertinsky, *Universities as Guardians of Their Inventions*, 2012 UTAH L. REV. 1949, 2013–14 (2012).

[175] *Id.* at 1964, 2015–16.

[176] *See* C. Steven McDaniel, *Protecting Biotechnology Trade Secrets in University and Industrial Research*, 16 HOUS. J. INT'L L. 565, 589 (1994).

It is important to note that despite potential legal solutions for protecting biological sequences, public policy concerns (raised in the *Myriad* amicus briefs) influence the ability of organizations to keep genetic information secret.[177] Because many educational organizations receive federal monies for research,[178] much of this research is covered by the public access policy for all government science funding agencies, which requires recipients to make available all data and resulting publications open to the general public through PubMed Central.[179] Private science research often utilizes

[177] *See Association for Molecular Pathology v. Myriad Genetics, Inc.*, SCOTUSBLOG, (2016), http://www.scotusblog.com/case-files/cases/association-for-molecular-pathology-v-myriad-genetics-inc/ [https://perma.cc/B43F-4SQX] (listing amicus briefs from a wide variety of petitioners opposing patenting DNA used for testing procedures). Please note: the ACLU has begun a second round of litigation against Myriad Genetics, this time seeking to invalidate its trade secrets. It is not unexpected that Myriad Genetics has sought to protect its data by alternative means. In this case, patients have sought access to health information via 45 CFR § 164.524 (the Health Insurance Accountability and Portability Act) that is part of the database that Myriad Genetics has stated contains trade secrets. *See generally* John Conley, *ACLU v. Myriad Genetics, Round 2: The Problem of Governance-by-Guidance*, GENETICS LAW REPORT (June 9, 2016), http://www.genomicslawreport.com/index.php/2016/06/09/aclu-v-myriad-genetics-round-2-the-problem-of-governance-by-guidance/ [https://perma.cc/2S5J-6H2D].

[178] *See* Art Jahnke, *Who Picks up the Tab for Science?* BOSTON UNIV. RES., http://www.bu.edu/research/articles/funding-for-scientific-research/ [https://perma.cc/RLR7-CR74] (last visited Oct. 15, 2016). The amount of federal funding significantly outweighs all other funding sources across universities.

[179] *Id.* (noting federal research for biomedical research is substantially higher than other investments, ranging between $25 and $30 billion per year); *see also* Charlotte A. Tschider, *Innovation in the Public Sphere: Reimagining Law and Economics to Solve the National Institutes of Health Publishing Controversy*, 1(3) J. LAW BIOSCIENCES 281 (2014) (describing the global economic implications of copyright on research publications for federally funded scientific research); Rebecca S.

public access databases, and not contributing any information back to these databases creates an asymmetrical relationship impacting the speed of genetic research.[180] The growth of intellectual property protection, though once aiming to drive economic growth, has resulted in the privatization of information originally planned to benefit the public and advance knowledge.[181] Despite public policy benefits for information and research sharing, substantial investments in biotechnological research without adequate legal protection may result in organizations preferring secrecy over sharing.

CONCLUSION

At present, no clear legal direction has been identified to holistically protect biological sequences. Although metaphors in *Myriad* indicate that either copyright protection or trade secret protection might be a possibility for organizations seeking to protect their investments, both options present significant issues. An independent database initiative may provide some protection for the information-gathering efforts of biotechnology organizations, but at this time, an immediate, viable database solution seems unlikely. While copyright protection significantly limits the ability to

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Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1672–73 (1996) (comparing the challenges in privatization versus full public ownership of patented inventions).

[180] Robert Cook-Deegan, John M. Conley, James P. Evans, & Daniel Vorhaus, *The next controversy in genetic testing: clinical data as trade secrets?*, 21 EUR. J. HUM. GENETICS 585 (2013); *see also* Roger A. McEowen, *Legal Issues Related to the Use and Ownership of Genetically Modified Organisms*, 43 WASHBURN L.J. 611, 637 (2004).

[181] Keith Aoki, Authors*, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain Part I*, 18 COLUM. J.L. & ARTS 1, 5 (1993).

protect individual elements of a DNA compilation (e.g., individual strains or the coding base pairs of biological sequences), increased use of trade secrets may impact future information disclosure and impede healthy competition. Absent Congressional involvement, the lack of clear legal guidance for simultaneously protecting financial investments and enabling disclosure will likely cause increased privatization and non-disclosure of information. Congress would be wise to focus on developing a reasonable option for legally protecting biological sequence investment while simultaneously promoting data sharing.

APPENDIX: FIGURES

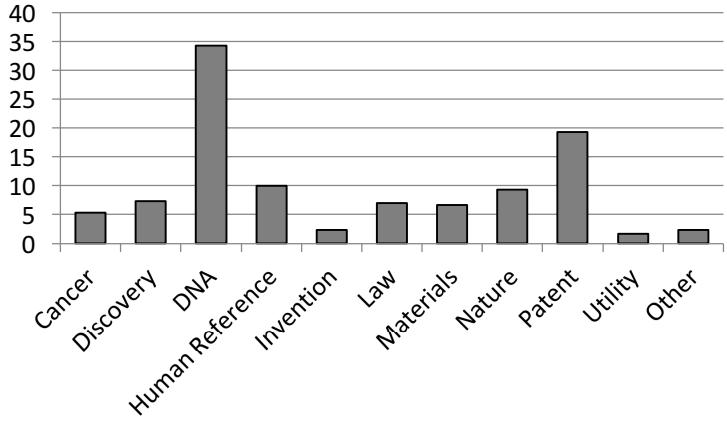

Figure 1: Total Word Counts

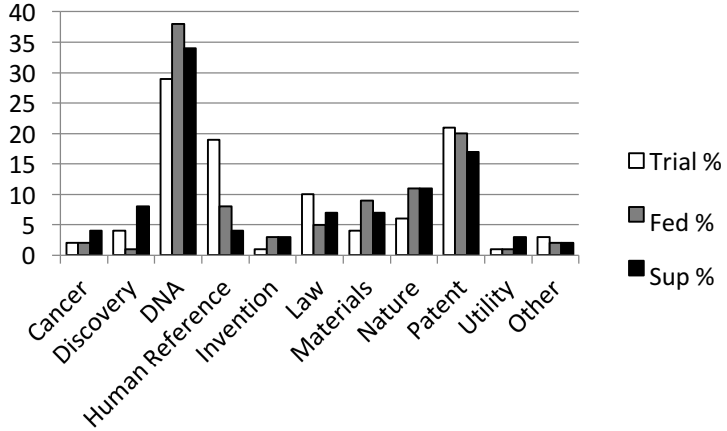

Figure 2: Word Count by Court

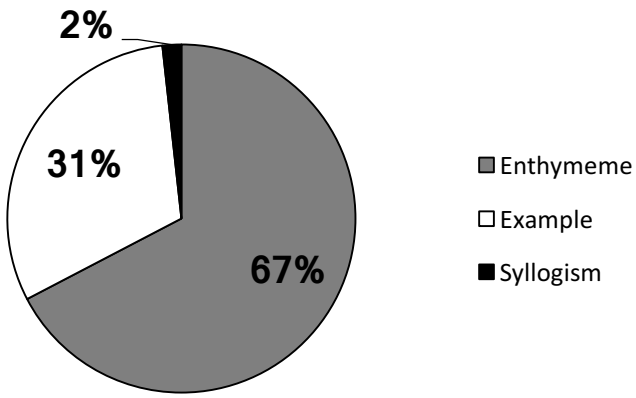

Figure 3: Logical Reasoning Across Courts

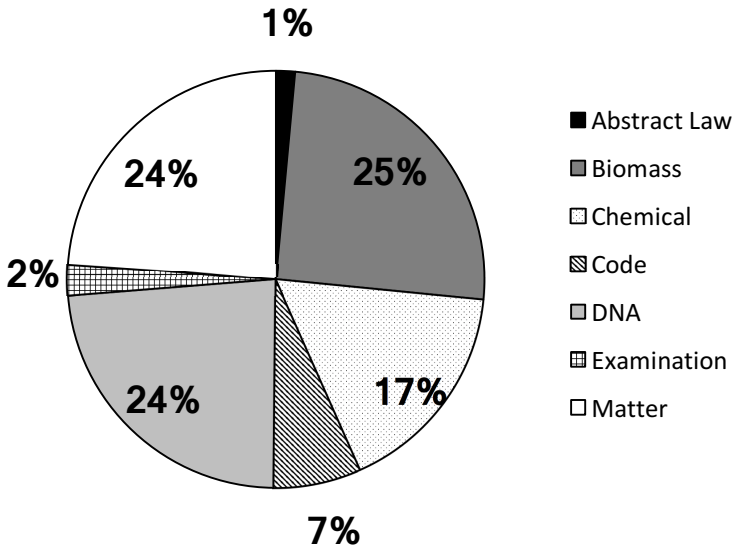

Figure 4: Metaphor Groupings Cross-Court

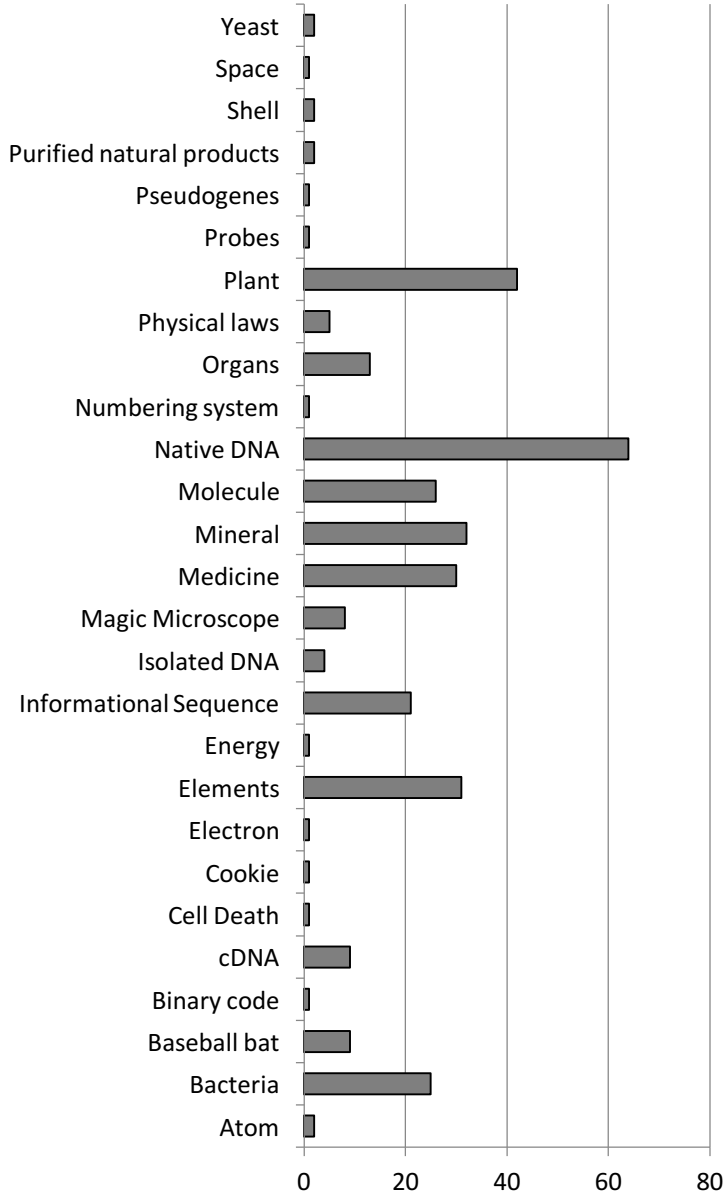

Figure 5: Court Metaphors