Response of U.S. University & College Technology Transfer to *AMP v. Myriad* (2013)

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ABSTRACT

The United States Patent and Trademark Office (USPTO) aims to stimulate and promote innovation, to strengthen the nation's industry and economy, and to maintain the United States' technological competitiveness on a global scale. One type of intellectual property protection offered by the USPTO is patents. Patent protection offers inventors a legal title to their innovation, as well as the right to exclude others from making, using, selling or importing their patented work for a term of 20 years. In exchange, the inventor agrees to publicly disclose information about their innovation. Prior to 1980, the patents of federally-funded research projects for small businesses and nonprofits, such as universities, were held by the U.S. government, resulting in billions of dollars of research innovation being unapplied for public use. The Bayh-Doyle Act marked a shift of patent titles and licensing responsibilities away from the government to the federally-funded research entities. This shift caused exponential growth in industrial innovation and "technology transfer" at academic institutions. In particular, patents of "natural products" skyrocketed in volume for the field of biotechnology. However, a string of Supreme Court decisions in the early 21st century, particularly the highly publicized *Association for Molecular Pathology v. Myriad Genetics, Inc.*, cast new uncertainty on the patentability of natural products. This study briefly reviews the patenting landscape of biotechnology leading up to *Myriad* and aims to provide greater insight as to the effects of the Supreme Court's decision at

the level of academic research institutions, as perceived by surveyed members of the Association of University Technology Managers (AUTM). Statistically significant results were achieved on data in the following six areas: (1) demographics of survey respondents, (2) patenting behaviors post-*Myriad*, (3) attitudes toward patenting (in general), (4) attitudes toward *Myriad*, (5) the use of certain patenting strategies post-*Myriad.* However, there was insufficient survey response on section (6)—attitudes toward those same strategies (perception of their effectiveness)—to make claims from the data.

BACKGROUND

Patent Law in the United States

Patent protection plays a vital role in the United States' economy. It stimulates industry and new job creation and helps to promote public access to better goods and services within the nation's free market system. Within this competitive economic atmosphere, having the opportunity to safeguard one's commercialization prospects and to gain a market advantage provides valuable incentives for new innovation. For research entities in particular, it helps them to maximize the return of grant investments and to apply the findings of their work to real-world applications through industry. In summary, patent protection creates a structure for technology transfer and regulation that encourages the following responses: disclosure of invention details rather than data secrecy; investment in research efforts; and further investment in the product development, marketing and commercialization of innovation (Crespi).

The process of patent acquisition can take several years from the time of the initial application submission. In order to receive a patent, the inventor must demonstrate that their claim meets certain standards for novelty (originality), inventiveness (non-obviousness), and

utility (useful application). Patents cannot be acquired for innovation that was formerly presented to the public or exists in "prior art" (works predating the application submission for the patent claim). When an inventor receives a patent, they have exclusive title and licensing rights to the innovation. This legal right entitles the inventor to exclude others from making, using, selling or importing their patented work for a term of 20 years. In exchange for this patent protection, the inventor must make a public disclosure of their innovation, including the "best most" of using the claimed invention. The tradeoff of legal protection for data sharing aims to promote innovative process, because other entities will be able to use information from the patent disclosure in order to further advance their own innovative works.

The economic value of a patent is derived from the tangible nature of the innovation in question (Crespi); therefore, the definition of "patent eligible" material is largely concerned with the application of ideas to inventions or processes rather than abstract concepts or research theories. This distinction excludes laws of natural or physical phenomena, such as the wind, from being patented, as these categories are considered to be non-exclusive expressions of nature and not the creation of any one person. The U.S. Supreme Court noted, "Without this exception [for natural phenomena], there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.' This would be at odds with the very point of patents, which exist to promote creation." (pg. 11 of AMP Supreme Court case). As technology advances, the boundaries of what subject material is "patent eligible" continues to be shaped by case law and by precedents set by the USPTO. Within the biological sciences, patents generally fall into one of the following four categories (Crespi):

Products	Marketed products and substances (e.g. "natural products", semi-synthetic penicillin, fermentation products)
Compositions	(e.g. new chemical mixtures for application in pharmaceuticals or in pharmaceutical or insecticides)
Processes and methods of use	Process in preparation; also use of new strains, new species, particular fermentation methods, etc.
Misc. Methods	Methods of treatment (e.g. herbicidal treatment, meat tenderizing, human/animal treatment) and testing (concerned with quality control)

Within the first category, controversy has arisen over the question of the patent eligibility for "natural products"—isolated or purified organic substances, found in or derived from nature. This area of research is one of great importance to the field of biotechnology. The difficulty of defining the patent eligibility of natural products stems from the distinction between actions of invention and actions of mere discovery. As previously stated, a patent requires novelty and inventiveness. Can natural products—such as nucleic acids, foods, bacteria, proteins and peptides, chemicals from natural sources including antibiotics and resins—be said to be "novel" when they naturally occur in biological organisms? Some individuals argue that nothing new has been created by the isolation of these natural products; the product has been merely separated from its naturally occurring state in an organism. Therefore, they do not meet the standards of novelty and innovation. On the other side of that argument, the isolation and purification of natural products enables a sense of "utility" that the product does not have within the organism. cannot exist within their natural state in an organism. This is claimed to be a form of innovation. For those on the former end of the argument, a blanket denial of all natural product claims may seem to be the clearest solution to defining patent eligibility in this area. However, the research process surrounding these natural products—of providing new tangible applications to the knowledge acquired on natural phenomena—is so akin to the procedure of typical innovation that this extreme of a path seems to contradict previously established precedent for what is patent

eligible. A 2004 IP resource for scientists and engineers provided the following non-exhaustive summary of patentable subject material for natural products:

> *"novel, useful and non-obvious microbes, plants, animals, natural and synthetic compounds, genes, proteins, DNA, RNA, recombinant cells, proteins expressed by genes in recombinant proteins, processes for recovery of proteins, processes for medically delivering recombinant proteins, and methods of altering natural properties of plants such as stress, disease or pest resistance." (Rockman).*

However, this summary has continued to become more nuanced and narrower, necessitating a continued reevaluation of the boundaries of patenting for natural products. The USPTO's 2019 Revised Patent Subject Matter Eligibility Guide had the following to say about natural product patenting:

> *"The Supreme Court has held that the patent eligibility statute, Section 101, contains an implicit exception for '[l]aws of nature, natural phenomena, and abstract ideas,'' which are ''the basic tools of scientific and technological work.' Yet, the Court has explained that '[a]t some level, all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,' and has cautioned 'to tread carefully in construing this exclusionary principle lest it swallow all of patent law.'" (USPTO)*

The Rise of Modern Biotechnology

The question of natural product patents is particularly relevant in the context of prominent biotechnological research landscape. The concept of biotechnology is not a recent one. It long predates this century, tracing as far back in history as 6000 B.C.E. with the use of yeast in beer production by the Sumerians (Rockman). This notion has continued to evolve over the centuries. In the modern age, the field of biotechnology has been marked by the use of recombinant DNA and the application of recombinant organisms to both industry and environmental projects.

In conjunction with Congress' Bayh-Doyle Act (discussed further in the following section), patents in biotechnology research skyrocketed after a 1980 Supreme Court decision determining that the bounds of patent eligibility encompassed "anything under the sun made by man", so long as the innovation met the requirements of novelty, inventiveness and utility (Rooksby). Shortly after this decision, recombinant human insulin, used in the treatment of type 1 diabetes, was commercialized for the first time. A wave of advancements ensued for process development in biotechnology, leading to the creation of new media, buffers, solutions and equipment involved in methods of protein production (Rockman). "Gene patents" of nucleotides coding for a specific protein skyrocketed in volume through the late 1990s. This onslaught of new biological products augmented the relevance of the "natural product problem" in patenting, particularly in regard to commercially-relevant agricultural and pharmaceutical research (Rockman).

Bayh-Doyle Act of 1980 // The Birth of University Technology Transfer

The surge of biological patent claims in the 1980s was further influenced by the Bayh-Doyle Act of Congress. Until this point, the U.S. government had the title and sole rights for licensing of federally-funded research projects, including those conducted at academic institutions. However, this system was leaving billons of research findings unused, "collecting dust on the shelves". Only a small percentage of these patented innovations was being licensed for industry, resulting in a very low return on public benefit for the billions of taxpayer dollars flowing into this research. With this new legislation, Congress shifted patent title and licensing responsibilities to the entities performing the government funded research. This change permitted small businesses and non-profit entities, including universities, to better maximize of the fruits of their federally-funded research endeavors (McDevitt), while the government retained certain royalty-free licensing rights for certain federal purposes (AUTM). The shift was largely motivated, not by the goal of benefitting the individual federally-funded entities, but rather by the desire to maximize the public value of research innovation. Two assumptions were prominent in driving this shift: (1) the economic supposition that research with potential commercial return would receive greater private investment and (2) the belief that these federally-funded entities would be able to industrialize a greater volume of patented innovation for the benefit of public use.

Indeed, the Bayh-Doyle Act succeeded in stimulating commercialization of patented innovation. Prior to the implementation of this legislation, less than 5% of the 28,000 federally-funded patents held by the U.S. government had been licensed for industry use (McDewitt). The government's exclusive title on federally-funded research had, in fact, caused a stumbling block for these research innovations to move outside of the lab and become useful in the public sphere.

By transferring the rights of ownership away from the federal government, Congress moved the responsibility of technology transfer and licensing to smaller entities, such as universities, which were better positioned to promote the real-work implementation of their research in industry. The Bayh-Doyle Act aimed—and succeeded—in funneling taxpayer-funded research back to contributing to a public good. This shift helped to maximize the return on billions of dollars poured by the government into federally-funded research, through agencies such as the National Science Foundation (NSF) and the National Institute of Health (NIH) (AUTM).

The Bayh-Doyle Act greatly impacted industry growth out of academic research institutions. Between 1980 and 2007, roughly 60% of academic biomedical research was conducted with some form of federal funding (Rai). The transfer of patent ownership encouraged research investments for products such as Gatorade®, the Breathlyzer®, the OncoMouse® (a genetically modified mouse used for research testing), numerous vaccinations and various diagnostic and therapeutic cancer treatments. (Rooksby, AUTM). The resulting rising patent volume from these academic institutions necessitated the growth of a new profession: university technology transfer. This field is described by the Association for University Technology Managers (AUTM) as "the process of transferring scientific findings from one organization to another for the purpose of further development and commercialization" (McDevitt). Today, Technology Licensing Offices (TLO) play an increasingly vital role in the management of academic research discovery and innovation.

Pros and Cons of Technology Transfer

Technology transfer professionals play a vital role in transforming the research in labs into commercial or publicly-accessible products or services through various means, including collaboration with or licensing to a private exterior company (AUTM, Pradhan). This

maximization of real-world research impact has great industrial implications. Public benefits of technology transfer include the economic creation of jobs, new industries and better products for public access. Over 4,000 companies have been birthed from university research since the passing of the Bayh-Doyle Act, particularly at a regional and local level near universities (AUTM). This growth in entrepreneurial innovation has stimulated the nation's economy and has pushed the United States forward as a competitive leading power on the global stage of innovation (AUTM). According to a 2015 report by the Organisation for Economic Co-operation and Development (OECD), the United States ranks first globally for number of biotechnology firms (11,367) followed by Spain (2,831) and France (1,950) (Phillips). For good reason, the collaborative effort of U.S. universities, the federal government and commercial businesses have been termed "the envy of every nation" (Tansey).

Despite these industrial benefits, concerns have been raised that the Bayh-Doyle Act has, in fact, created greater conflicts of interest in research. A university emphasis on profit-making may reduce support for its "fundamental discovery" research. Bias, or at least the appearance of bias, can also create public mistrust of medical research efforts (Tansey). For example, companies with a vested economic interest may use their influence to censor research findings that have unfavorable implication for their own business. Reports of this type of information suppression tarnish public opinion of research. In addition, federal funding of university biomedical patents can become controversial if these universities later assert their patents against individual commercial entities (Rai). Lastly, there exists a concern of data sharing in relation to patent protection. The proper public reporting of patents, their licensing and their practical use would lead to a strong, thriving database for innovation; however, there have been concerns that federally funded academic patents do not encourage an open sharing of information. Rather, the

economic advantage of hoarding research discovery in order to receive future patents is argued to have become a roadblock to innovation (Rai). Each of these areas of concern continues to need to be addressed and balanced with the promotion of research innovation.

While the benefits of licensing and funding are often emphasized, the revenue received from university patents is far from lucrative (McDewitt). The role of technology transfer is not simply commercial. Within the university, tech transfer promotes a culture of innovation both with faculty researchers and with students themselves. Practical experience in research has been shown to strengthen students' academic success, as well as exposure them to the foundations of intellectual property creation (McDewitt). Technology transfer also aids in the dissemination of public knowledge through education outreach, journal publications, healthcare programs, etc. (Coticchia). Demonstrating the real-world application of university research helps the public to better understand its value, even if they do not understand all of the details of the work. This public perspective can aid universities in their support and fundraising outside of federally-supported grants.

Precedents to *Association for Molecular Pathology v. Myriad Genetics, Inc. (2013)*

The boom of biotechnical innovation after the Bayh-Doyle Act elevated the importance of natural product patenting, and several precedents began to narrow the boundaries for what products of nature constituted "patent eligible" subject matter. For example, a claim for an isolated and purified product from a raw plant was rejected by the USPTO because the product deemed to be merely produced in nature (Crespi). Similarly, another claim to an alcoholic extract was deemed patent-ineligible cases since its composition was the same of that found in nature and it did not demonstrate sufficient "invention" (Crespi). Attaining a natural product patent is largely contingent on an individual's ability to distinguish between the patent claim and what is

found inherently out in nature. Mere stabilization of a compound does not necessarily lend patentability to it, nor does the isolation of a compound whose properties are the same as the natural substance from which it was isolated (Crespi).

The boundaries of "invention" for natural product patent claims is tricky. In 1951 and 1955, two patents were approved by the U.S. Patent & Trademark Office for vitamin B12 (US Patent No. 2,563,794), a supplement used in the treatment of pernicious anemia. This decision was made on the grounds that, although B12 is derived from nature, great steps are necessary in order to make the vitamin's activity useful in a manner not possible in its natural form. This process was deemed to constitute more than just a mere isolation of the vitamin (Crespi). In the same year as Bayh-Doyle (1980), the Supreme Court heard the case of *Diamond v. Chakrabarty*. Through this case, the Supreme Court ruled that a "living, genetically altered (recombinant) microorganism" was eligible material for a patent (Rockman) due to modifications that distinguished it from products found in nature. The aftermath of the *Chakrabarty* decision was an outright explosion of biotechnological patenting. Regulations for the patenting of living organisms was further clarified by the U.S. Patent Office in the wake of *Ex parte Allen*, 2 USPQ 2d 1425 (Bd. Pat. App. & Int. 1987) after the rejection of a patent claim for a man-made oyster for failing to meet standards for "non-obviousness". The Patent Commissioner affirmed the following in a public pronouncement: "The Patent and Trademark Office now considers non-naturally occurring non-human, multi-cellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. §101 (the patent statute provision that defines patentable subject matter)."

Of particular later relevance to the *AMP v. Myriad* case were precedents established for the patenting of nucleotide-based and genetic materials. Before the case's decision was released,

public expectations leaned toward the Supreme Court finding some sort of exception for the patenting of genes (portions of DNA that code for proteins), keeping in line with nearly 30 years of patenting precedent that had allowed for "gene patents" (Graff). Nucleotide-related patenting had experienced a phase of exponential growth from the 1980s through 1998 or 1999, corresponding to the early sequencing of both the human genome and that of other species, (Graff). The early 2000s saw a shift away from simple isolated DNA or RNA patents, perhaps due to difficulties in creating commercial profit from them (Graff). In fact, several of Myriad Genetic Inc.'s patents in question were already set to expire in 2015—a mere two years later—regardless of the Supreme Court's ruling (Graff). This movement away from gene patents reduced the direct relevance of the *Myriad* ruling to genetics. However, it had a greater purported influence on natural product patenting as a whole.

The United States Supreme Court case of *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013) was the third in a triad of cases related to natural product patenting, following *Bilski v. Kappos* (2010) and *Mayo Collaborative Services v. Prometheus Laboratories* (2012) (Rai). *Bilski v. Kappos* narrowed the definition of patentable subject material for processes. This case instituted a "machine" or "transformation" test, which required that that the process in question either be designed to be carried out by a machine or be used to transform something to a different state (Offit). In the subsequent 2012 ruling of *Mayo v. Prometheus*, the Supreme Court ruled on the legality of two patent claims held by Mayo Collaborative Services on therapeutic thiopurine drugs. This decision found that the mere isolation of these drugs was a routine scientific procedure (Rai); therefore, their claims did not demonstrate sufficiently substantial "innovation" to distinguish the drugs from naturally occurring phenomena (Offit). In its summary of this ruling, the Supreme Court cited the following from *Diamond v. Diehr*

(1981): while §101 of the Patent Act exempts natural phenomena, laws of nature and abstract concepts from being patented, "an application of a law of nature . . . to a known structure or process may [deserve] patent protection," so long as that application extends beyond a simple restatement of the unpatentable abstract concept or law of nature with the words "apply it" following it (Mayo Collaborative Services v. Prometheus Laboratories, Inc). The Supreme Court's *Mayo* ruling additionally determined the relationship between dosage and toxicity/effectiveness of a drug for patent eligibility, a distinction later relevant to antibody patenting (Murphy & Heithaus). The reasoning processes behind these two cases—*Bilski v. Kappos* and *Mayo v. Prometheus*—were particularly impactful to the evaluation of patent eligibility claims for subsequent the *AMP v. Myriad* case.

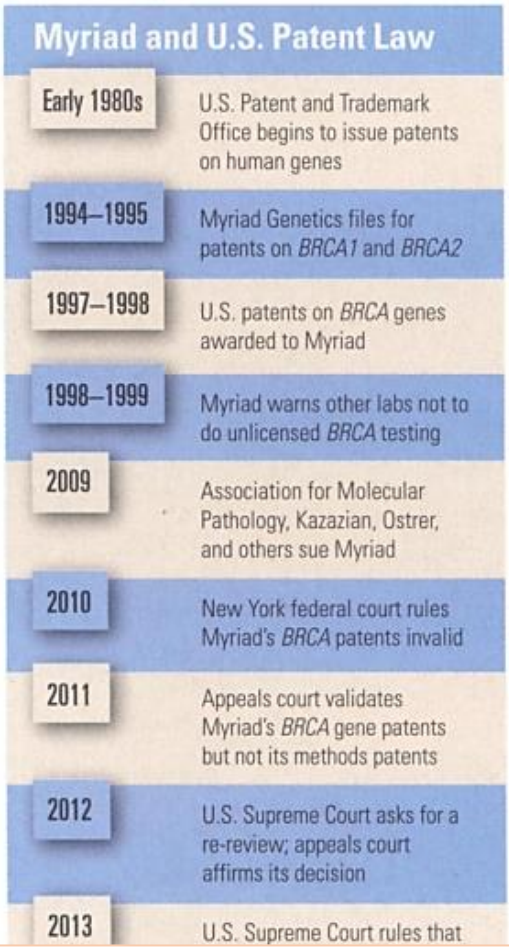


Figure 1: Summary of *Myriad* case and BRCA1/2 patents

PHOTO FROM MARSHALL, "Supreme Court Rules Out Patents on 'Natural' Genes"

Facts / Ruling of *AMP v. Myriad*

The Supreme Court's *Mayo* ruling cast uncertainty on the viability of a Federal Court ruling in *Association for Molecular Pathology v. United States Patent and Trademark Office* (Patel). This case had addressed the patent eligibility of isolated human DNA sequences, which—like Mayo's thiopurine drugs—were used for diagnostic medical practices, namely for assessing the risk of breast and ovarian cancer. Due to the similarity of the cases, the *Myriad* ruling was selected for review by the Supreme Court.

The plaintiffs of the Myriad case were a group of doctors, scientists, researchers, and patients represented by the American Civil Liberties Union and the Public Patent Foundation (PUBPAT). They argued that gene patents held by Myriad Genetics, Inc. —for Breast Cancer Susceptibility Genes 1 and 2: respectively BRCA1 and BRCA2—caused harm due to the restrictions the company was able to impose on research and patient treatment. Mutations to these genes serve as significant indicator for a woman's risk of developing breast or ovarian cancer. After Myriad received patents for these genes, the company chose not to license their patent, precluding any other group from isolating these genes. Their resulting monopoly on diagnostic tests involving BRCA1/2 allowed the company to amass nearly $9 million in monthly revenue from their own BRCA diagnostic tests (Jaggar). However, in maintaining this economic advantage, Myriad Genetic, Inc. had—according to the plaintiffs—significantly harmed public interest. In addition to (a) limiting patients' access to these tests due to their high cost, Myriad's monopoly also (b) hoarded data rather than releasing it for public and research use and (c) prevented other organizations from creating alternative and improved diagnostic methods for the BRCA1/2 genes. Myriad's monopoly-like tendencies pushed against the norm of university-held diagnostic patents to allow for outside nonexclusive licensing, bringing much public attention and emotional force behind the Myriad case (Rai).

Before advancing to the U.S. Supreme Court as *Association for Molecular Pathology v. Myriad Genetics, Inc.*, this case was heard in Southern District Court of New York and the United States Court of Appeals for the Federal Circuit. Through these lower court trials, a variety of interesting analogies were made for the natural product patent eligibility problem. One analogy compared the situation of a gene within a DNA sequence to that of a mineral stuck within a rock. While one judge contended that the mere extraction of a mineral from a rock

would not constitute "invention", Myriad argued that—assuming novelty and non-obviousness—the mineral would be patentable if human ingenuity was required to extract it, citing §101 of the Supreme Court's prior *Chakrabarty* and *Funk Brothers* rulings. Myriad proposed an alternative analogy for the isolation of a gene from DNA: a tree and a baseball bat. They argued that the baseball bat exists within the tree, which itself exists in nature. It is the human ingenuity required to "extract" the baseball bat from the tree that makes it eligible for patenting. In a similar manner, Myriad argued that the extraction and purification of a single gene from DNA required sufficient human ingenuity to meet the requirements of valid patentable subject material (David).

On June 13, 2013, the Supreme Court reached its decision. The majority opinion of eight justices—Justice Scalia filed a separate concurring opinion—stated that the mere isolation of DNA, or the modifications made for the sole purpose of isolation, did not constitute a level of innovation necessary to distinguish native (genomic) DNA, also known as gDNA, from what occurs in nature. This distinction affirmed that the isolation of gDNA was akin to the analogy of extracting a mineral from rock. Natural resources within extractive industries are considered non-patentable (Evans); therefore, Myriad's gDNA patent claims to BRCA1/2 were invalidated. However, the Supreme Court ruled that complementary DNA (cDNA) was, in fact, a patent eligible subject material. cDNA refers to synthetic DNA that mirrors the sequence of gDNA and from which introns (the portions of sequence that do not code for a gene product) have been removed (Offit). Therefore, Myriad's gene patents for cDNA were affirmed.

Support for the *Myriad* ruling

The *Myriad* decision reframed the legal framework of medical genetics (Evans). It surprised many technology transfer professionals and patent attorneys, essentially overturning 30 years of allowance of gene patents by the USPTO. Despite this unsuspected shift in gene patent

eligibility, the *Myriad* ruling was largely cited as a victory by academic researchers (Chandra). Their ruling was in line with a concession presented in the reasoning for the prior *Mayo* decision: "the subject matter test is rooted in a policy concern that patents covering board subject matter will "preempt" too much future research" (Rai). By removing Myriad's monopoly on BRCA1/2, the Supreme Court opened an avenue for other companies and researchers to begin creating alternative medical diagnostic tests for these genes. The *Myriad* ruling on the patent ineligibility of gDNA also assuaged broader concerns that gDNA patents would prevent whole genome sequencing (Rai). Francis Collins, director of NIH at the time of Myriad, supported the Court's decision by emphasizing "Our position all along has been that patenting DNA in its natural state does not provide any benefit to the public. We can breathe a big sigh of relief that [law- suits] will no longer threaten to inhibit the progress of DNA research" (Marshall). However, much uncertainty was created by the Court's second ruling on the standing of cDNA—exactly how much modification was necessary to denote true "innovation" rather than "discovery", since mere isolation was deemed insufficient to protect gDNA by patents?

By affirming the patent eligibility of cDNA, the Supreme Court may have also stepped back a bit from their prior *Mayo* decision, which classified the application of a routine scientific procedure as insufficient to confer "innovation" to what was otherwise a natural product. cDNA claims, such as those upheld for BRCA1/2, rely on intron removal, a process which might also be categorized as a routine scientific procedure (Rai). The Supreme Court did not articulate in it majority why cDNA patent claims were less problematic than those for gDNA (Rai). However, it has been noted that cDNA poses a lesser risk of being used to obstruct future research and allows scientists to freely segment natural DNA (Cartwright). The Solicitor General and geneticist Eric Lander purported that, for research purposes, cDNA claims can general be more easily worked

around than gDNA claims (Rai). In addition, from the perspective of prioritizing and incentivizing innovation, cDNA patents are generally considered to be more valuable than unmodified gDNA patents for commercialization prospects (Rai), due to being shorter and easier to work with within a lab setting than gDNA.

The issues of public attention surrounding Myriad Genetic, Inc.'s monopoly (including high price, limited access to diagnostic test depending on one's insurance, etc.) were not directly addressed by the Court, which chose instead to focus its response on the question of innovation and broader economic incentives (Rai). However, the Myriad decision did impede monopolies via a singular hold on a gDNA patent. Without this particular economic advantage, companies like Myriad would be pressed to maintain their competitive edge by improving their diagnostic product (for example, by enhancing quality, affordability, turnaround time or clearness of clinical reports) (Rai). This economic incentive was expected to notably benefit the patient and public consumer.

Critics of the *Myriad* ruling

Directly following the Myriad decision, certain leaders in the biotechnology industry posed the concern that it could "create business uncertainty for a broader range of biotechnology inventions" (Marshall). The rationale of the Supreme Court threw into concern patents on other natural materials, such as "human insulin, human cell receptors, warfarin, enzymes, bacteria, microbes, and many other biological entities" (Marshall). In addition to direct gene sequences, patents of antibodies for therapeutic applications were thought to be in danger under these new distinctions of non-patentable subject matter (Ponraj), as well as patents for epitope residues (Deng). Beyond its applications to diagnostics and gene patenting, the Supreme Court's ruling was expected to influence other prominent areas of research, such as isolated protein and

embryonic stem cell patents. In addition, the Myriad ruling in a case of human genes would likely be applied more broadly to the genomes of other organisms, including agriculturally significant plants (Ledford).

Although some university researchers strongly supported the *Myriad* ruling, others had concerns of its implications to biotechnological advancements. Included among these were concerns that the Court's affirmation of cDNA patents would still impede labs from conducting research if they were to discover that the cDNA relied upon for their project was already patented by a company (Cartwright). In addition, the lack of innovative incentive through patent protection of natural products was feared to reduce the economic investment made in biotechnology research. Critics of the *Myriad* decision worried that such a lack of funding would impede research advancements and commercialization at universities, an end in total contrast to the USPTO's aim to promote innovation.

Concerns regarding proprietary databases

The response of Myriad Genetics, Inc. in the wake of the 2013 Supreme Court decision also cast broader concerns on information sharing in research. Even after losing its gDNA patents, Myriad retained a powerful advantage through the accumulation of patients' biodata in a privately-controlled, proprietary database. While contrary to the university push toward open science and data access for the support of research progress, the financial motivation of this strategy is understandable. Without the incentive of patents, laboratories who openly share their research data are at an economic disadvantage. Allowing public access to the databases they have had to pour money into to create would reduce their ability to profit from it. It makes more sense for them to secure the data for themselves and aim toward funneling the knowledge toward a commercialized application (Evans) Therefore, the question becomes one of reducing financial

loss that comes from the deep investments necessary to construct these databases. This system, intensified by a reduced ability to obtain patents, ultimately discourages data disclosure.

This encouragement of proprietary databases has more than just economic implication. The system of data access advanced by the Myriad decision is doubted to promote an efficient, practical management of the "natural resource" of genomic information. The population of individuals having their genome sequences is a limited resource pool, as it excludes 10s of millions of people who may not have access to such testing, have no medical need for a genetic test, or do not express a personal curiosity in their genetic sequencing. Therefore, fragmentation of proprietary genetic databases threatens to create barriers to discovering important genotypic-phenotypic relationships. If sustained, this practice could significantly affect the quality of the investment return for these genetic research projects. (Evans). Professor Barbara Evans at the University of Houston Law Center compared the mining of the human genome to the exploitation the East Texas Oil Field in the early 1900s. By 1931, 80-90% of obtainable oil was permanently lost underground due to the fragmentation of various enterprises all seeking to separately mine the ground without coordination with one another. This gross wastefulness of a natural resource was ultimately contrary to the best interest of the public. In a similar manner, the current patent landscape's influence on data disclosure may encourage comparable wastefulness.

Technology transfer: where to go from here?

As previously mentioned, patent ownership by universities post-1980 helped to stimulate innovation and national competitiveness in the field of biotechnology (Rai). However, the trend of the past 20 years is leaning toward a future in which patents are a less profitable ("diminishing returns") means of protecting one's innovation (Rai). The Supreme Court's decision on *Myriad* caused great uncertainty within the technology transfer community as to the patent eligibility of

natural products. The ruling contained many ambiguities. For example, how many modifications would be necessary to establish a molecule sufficiently different from that of Myriad's BRCA1/2 cDNA sequences? In the rise of uncertainty post-Myriad, patent attorneys turned to recommending new methods of protection for innovation rather than a reliance solely on patents, including protection of an innovation by trade secret and a multitude of modifications to the naturally occurring DNA or proteins in question (Ledford). Advantages to trade secrets include no requirement of public disclosure of the claim, such as is required for patent acquisition, and no time limit to the claim as long as the secret is maintained (Chand).

SURVEY OF AUTM MEMBERS – UNIVERSITY & COLLEGE STAFF

Evaluation of *Myriad* impact: Research Methodology

Exempting instances of research into targeted therapeutics—such as those offered by Myriad Genetics, Inc.—at the time of the Supreme Court's ruling, little objective evidence existed to support the claims that gene patents impeded basic scientific research (Offit). Claims were made on both sides as to whether the *Myriad* decision would ultimately promote or impede greater innovation, especially in regard to natural products. Due to the impact of technology transfer in the growing field of biotechnology, this question has been of particular importance to academic research. Through AUTM, a string of economic evaluations has been conducted through survey responses to collect quantifiable data on 1996-2015. Rather than collect additional economic data, this study focused on qualitative data collection with three goals: to evaluate (a) the current attitudes of technology transfer professionals at academic institutions

(universities and colleges) toward *Myriad*'s impact on their profession, (b) its impact on natural product patenting and (c) the success of new strategies employed to protect innovation.

This study chose to focus solely on technology transfer personnel who are directly employed by a U.S. University or College. Other small business and nonprofit entities—namely hospitals and research institutes (HRI)—have been demonstrated to have similar patenting tendencies to universities and colleges and close ties with their personnel (Pressman). However, the technology transfer environment is different due to the additional emphasis on cultivating an educational, entrepreneurial culture with both faculty researchers and students. While commercialization is an important aspect of technology transfer, it is not necessarily the primary focus for University and College research innovation. The focus of HRI groups is heavily skewed toward economic impact. According to an economic review released in 2017 by the Association of University Technology Managers (AUTM), HRI's reported both a higher average of License Income Received and of Running Royalties than did Universities and Colleges. Due to the stronger bias of HRIs toward an economic emphasis, AUTM members from this category were excluded from the study. In addition to personnel of independent research institutions and hospitals, the following categories of AUTM members were also removed from evaluation for this study: private industry members, attorneys and legal firms, students and faculty, professionals residing outside of the United States, and public communications personnel / office managers from university and college tech transfer offices (positions that do not deal directly with patenting). The remaining population of interest – approximately 900 individuals – comprised staff from both university and college technology transfer offices who held membership in AUTM. For the remainder of this paper, the term "university" will be used to refer generally to both university and college academic institutions.

The selection of the sample population aimed to reduce participation bias (resulting from a lack of survey response) and collect representative data of the population of AUTM members in university and college tech transfer. Originally, the survey was going to be sent to all ~900 of the previously determined population. However, a great discrepancy was identified in the number of staff employed between the various academic institutions who were represented in AUTM. Some university/college tech transfer offices had only 2-3 staff with AUTM membership; others had upwards of 20. With this great of a difference, the staff of larger tech transfer offices could dramatically skew the results of the survey if there were a high response from those institutions. Therefore, in order to better control for the influence of tech transfer offices that employed significantly larger staffs, only up to five staff members from any university/college were invited to participate in the survey for this study. The limit of five participants aimed to maximize the chance of receiving at least one response from these institutions while keeping their potential influence on survey data within range of that of smaller tech transfer offices. The five survey recipients from each large tech transfer office were selected randomly. From the remaining population of ~900 AUTM members, contacts were sorted by university/college, each was assigned a number, and then five survey recipients were selected using a random number generator. After this process, 737 employees of U.S. universities and colleges were identified for the target population.

Each individual selected for this study received an email inviting them to participate in a Qualtrics survey of 18 question sections regarding the impact of *Myriad* (2013) on academic technology transfer. Data collection occurred over 13 days (28 March 2019 at approximately noon until 10 April 2019 at 11pm). During this time period, four reminder emails were sent through the email list, inviting the eligible AUTM members to participate. Of the 75 respondents

who consented to participate in the survey, 9 were removed from analysis due low familiarity in the subject matter (determined by a response "Not knowledgeable at all" to questions of their familiarity with a) the U.S. Patent system [Q1] and/or b) *Association for Molecular Pathology v. Myriad Genetics, Inc.* [Q3]. An additional four respondents elected to discontinue participation after the first few questions. After removing these individuals, the remaining sample size for data analysis was 62 respondents. This system of participant selection may have resulted in more than one staff member responding from any given institution. However, this concern was outweighed by that of low survey participation and insufficient data.

Findings & Discussion

The survey that was sent out focused on collecting data in the following six areas: (1) demographics of survey respondents, (2) patenting behaviors post-*Myriad*, (3) attitudes toward patenting (in general), (4) attitudes toward *Myriad*, (5) the use of certain patenting strategies post-*Myriad*, and (6) attitudes toward those same strategies (perception of their effectiveness). Of these, the first 5 sections received sufficient survey response for a statistically significant data analysis, but section 6 encountered several problems. Firstly, the response to section 6 was too low for a student's t-test analysis. In addition, there appears to have been confusion as to the nature of the question, likely occurring from the setup of the survey. Due to these issues, this study disregarded section 6 for further data analysis, although the responses are shown on pages 48-49 next to the responses from section 5.

As expected within the demographics section, a large percentage of the survey respondents (88.70%) had a STEM background in higher education (within fields including biology, chemistry, mathematics, physics, and engineering), with 53.23% holding a doctorate. The range for years of experience in technology transfer was quite large: ranging from 1 to 35.

Due to this wide range in years of experience, the demographic of individuals who were working within the field of technology transfer before the *Myriad* ruling (prior to 2013) and those who began tech transfer employment afterward was split 43 to 21 (67.19% to 32.81%). However, the majority of respondents (90.32%) agreed that they would be comfortable explaining the *Myriad* case to a layperson [Q4-1].

Those individuals who *had* worked in tech transfer before the *Myriad* ruling were presented a question [Q9] regarding the patenting behaviors of their university of employment for natural products pre- and post-*Myriad*. Of these respondents, none claimed an increase in natural product patent claims since the *Myriad* ruling. The majority of respondents (73.17%) for Q9 claimed of slightly lesser or substantially lesser number of natural product patents pursued post-*Myriad*. This trend is consistent with the early projected outcomes of the *Myriad* decision: a decrease in natural product patent pursuit. Questions regarding the patenting practices of universities post-*Myriad* [Q10-13] were presented to participants of all years of tech transfer experience. Consistent with the response to Q9, the majority of total survey respondents (82.14%) claimed that their university had chosen on at least one occasion to not pursue a natural product patent due to *Myriad* restrictions [Q13]. This can likely be attributed to economic concerns of investing money into a claim that will not result in obtaining a patent. Only a small minority of respondents cited the invalidation of a natural product patent (4 respondents, 9.09%) [Q12] or a prior/ongoing dispute of a natural product patent claim (9 respondents, 18.37%) [Q11] on the basis of *Myriad*. Although these percentages may seem low, they are arguably quite significant. Due to the high associated legal fees, these processes (particularly the invalidation of a patent) are rarely pursued for any type of patent. Therefore, the frequency of respondents citing an invalidation or dispute of one of their natural product claims was higher than expected for this

size of a sample group (62 respondents). On the question of whether the majority of the natural product claims pursued at the respondents' universities of employment post-Myriad had received approval, 76.09% of respondents answered "no". These findings seem to support a general decrease in both natural product patent pursuit and acquisition for university tech transfer offices.

In regards to patenting in general, the majority of respondents classified themselves as "very" or "extremely knowledgeable" of the U.S. Patent system compared to other tech transfer professionals [Q1]. A majority also agreed to having a confident understanding of U.S. regulations that affect patenting [Q2-1]. Respondents demonstrated a strongly favorable response to the impact of patents on research progress and investments [Q14-1,3]. The majority also agreed to the statement that "patents promote economic investments into producing / marketing new products" [Q14-2]. These responses were consistent with those expected of professionals in the technology transfer field.

More specifically regarding *Myriad*, the responses supported a fairly nuanced view toward *Myriad* that slightly leans in favor of the ruling's critics. Respondents were split fairly evenly when presented the statement "The impact of Myriad on university tech transfer has been solely negative", with a slight majority agreeing [Q15-4]. For the statement, "*Myriad* promoted research progress by allowing broader study/use of some genes" [Q15-3], respondents were split again, with a slight majority disagreeing. However, the majority of respondents (77.42%) did agree that post-*Myriad*, "natural product patents are a risky university investment, due to the likelihood of future patent invalidation" [Q15-2]. This response was particularly interesting, considering that less than 10% of respondents responded that their university had actually had a natural product patent invalidated [Q12].

In the wake of *Myriad*, a great deal of uncertainty surrounded patent protection for natural products. The ruling stood at odds with years of USPTO precedents, which had largely permitted gene patents such as those held by Myriad Genetics, Inc. for BRCA1/2. Patent attorneys began recommending new strategies for drafting patent claims, as well as alternative methods of protection for innovation besides just patents. The following six strategies were recommended specifically for DNA technologies in an educational web seminar through *Technology Transfer Central*: "Analyzing and Adapting to the Supreme Court's Myriad Ruling" (Noonan):

Patenting strategy	Majority Response
Q16-1 "Reissued an existing patent to narrow the scope of the claim"	The majority of respondents had not used this strategy
Q16-2 "Protected specific claims with trade secret rather than patent"	Respondents who had not used this strategy constitute a small majority
Q16-3 "Made a generic disclosure of modifications rather than giving specific examples"	Respondents who had not used this strategy constituted a small majority
Q16-4 "Sought patent for isolated [and/or modified] cDNA copy of a nucleic acid"	Respondents were split pretty evenly between "Yes" and "No"
Q16-5 "Sought patent for cDNA-specific oligonucleotide"	Respondents were split pretty evenly between "Yes" and "No"
Q16-6 "Distinguished a nucleic acid patent claim from that of a natural product using labeling, cross-linkage or linkage to 'x' (x = biotin, fluorophore, etc.)	The majority of respondents had used this strategy

As previously stated, due to low response and the appearance of confusion for at least some respondents on Q17, data on perceptions toward these patenting strategies cannot be

considered statistically significant; as such, any differences between "Yes" and "No" responses cannot be said to be more than expected variation. Perhaps the exact patenting strategies detailed in this question, while encountered by university technology professionals, are more directly the concern of the patent attorneys with whom they work. A potential future avenue of research might be to explore a more quantitative approach to this question through literature review of the actual university natural product patent claims.

Due to the large sample size of respondents for sections 1-5, much of the data was determined to be statistically significant based on the assumptions of the Central Limit Theorem. However, there are several factors that may prevent the surveyed population from being an accurate representation of the desired population of interest: AUTM members who are professionals in university technology transfer. For example, due to concerns for keeping survey responses anonymous, respondents were not asked the name of their university/college of employment. For those academic institutions of smaller staffs with AUTM membership, this information alone could have revealed their identity. However, without this information, this survey could not take into account differences such as the level of emphasis for any academic institution on research involving natural products, or the economic resources and funding uniquely available to the different institutions. The survey may also have a nonresponse bias if certain segments of a population (for example, the technology transfer offices with significantly larger staffs) were not represented by the respondents who took the survey.

Sections 1-5 of this study achieved statistically significant results; however, as mentioned above, several variables may have prevented the sample population from fully representing the target population. In addition, while this study focused on the impact of *Myriad* on university and college natural product patenting, this is by no means an isolated issue. As covered in the

background, several important cases led up to the *Myriad* decision and carried with them their own precedents for patenting natural products. While the results of this study point to certain influences of the U.S. Supreme Court's *Myriad* decision, it is by no means the single causal base for today's natural product patenting environment. However, the *Myriad* case is undoubtedly an important landmark in the clarification process for the patentability of "natural products" within the advancing biotechnology industry.

QUALTRICS: Pre-Survey Consent Form

Purpose: In 2013, the U.S. Supreme Court's ruling in "*Association for Molecular Pathology v. Myriad Genetics, Inc.*" necessitated a change to patenting strategies for "natural products" by all U.S. entities, including universities. The purpose of this study is to investigate the impact of this ruling on the ability for university technology transfer offices to obtain "natural product" patents.

What to Expect: You have been invited to participate in this research project as a member of the Association of University Technology Managers. This survey on the online Qualtrics platform has been designed to assess impacts of *Myriad* (2013) on natural product patenting. Information gathered from this survey will only be reported in aggregate form. Aggregate data from this survey will be used for a written undergraduate Honors thesis and subsequent thesis defense on the Oklahoma State University campus, and may also be used for future publication. Participation is completely voluntary. Participants can withdraw from the survey at any time without reprisal or penalty. You will be expected to complete the questionnaire once. It is expected to take no more than 5 minutes to complete.

Risks: There are no risks associated with this project which are expected to be greater than those ordinarily encountered in daily life. Your participation in this survey is completely voluntary and confidential. You may choose to answer only some questions, or to withdraw your consent and participation in this research survey at any time.

Benefits: No direct benefit is anticipated for survey participants. By acquiring this data, the researchers will be able to produce a better academic understanding of natural product patenting at university tech transfer offices and the impact of *Myriad (2013)* on these practices.

Compensation: Participants will not receive compensation for participation in this survey.

Confidentiality: This survey is anonymized to not record any personal information and to remove contact association. All survey data will be stored on a password protected computer, and only the researchers will have access to these records. Information gathered from this survey will be reported in aggregate form.

If you choose to participate: You have the right to discontinue the survey at any time without penalty, as it is voluntary. If you agree to participate in the web research survey, click on the following Internet address to continue:

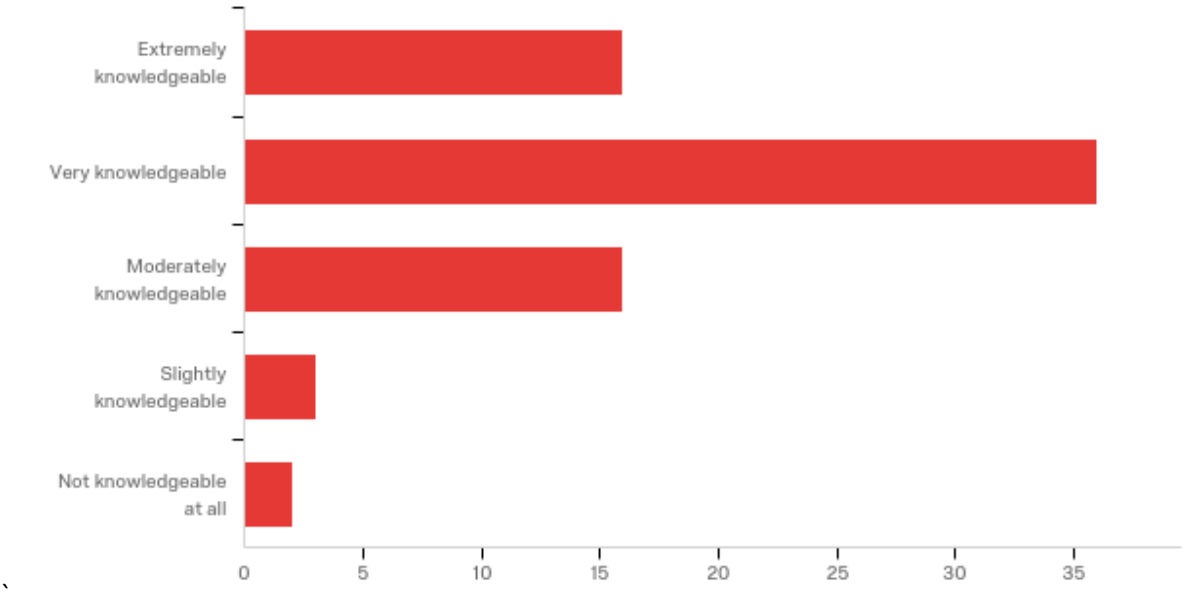
By clicking below, you are indicating that you freely and voluntarily agree to participate in this study and you also acknowledge that you are a member of the Association of University Technology Managers.

Answer	%	Count
I consent	100.00%	75
I do not consent	0.00%	0
Total	100%	75

NOTE: Two individuals who consented to the study later opted to discontinue after a few questions.

QUESTION PURPOSE:
IDENTIFY AND REMOVE RESPONDENTS WITH LOW FAMILIARITY

Q1 - Please rank your familiarity with the U.S. Patent system compared to other tech transfer professionals:

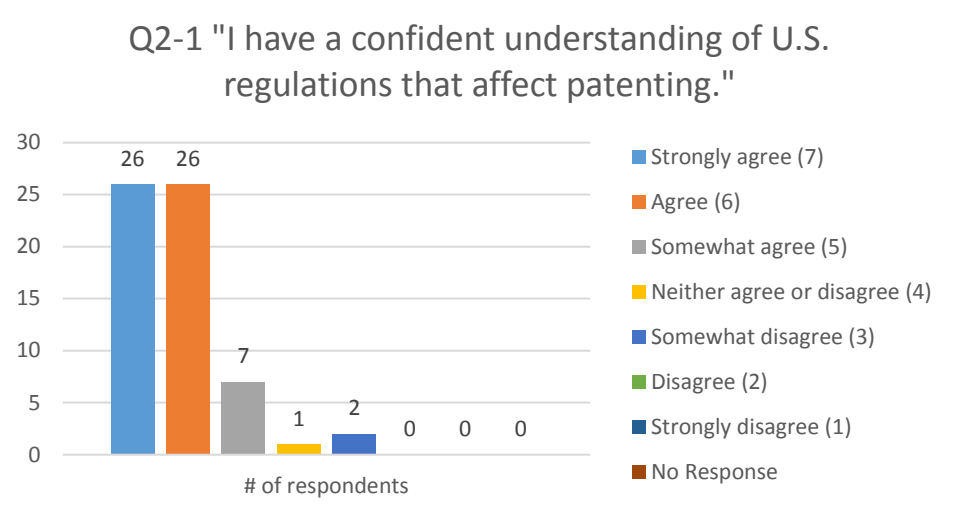


Minimum	Maximum	Mean	Std Deviation	Variance	Count
1.00	5.00	2.16	0.91	0.82	73

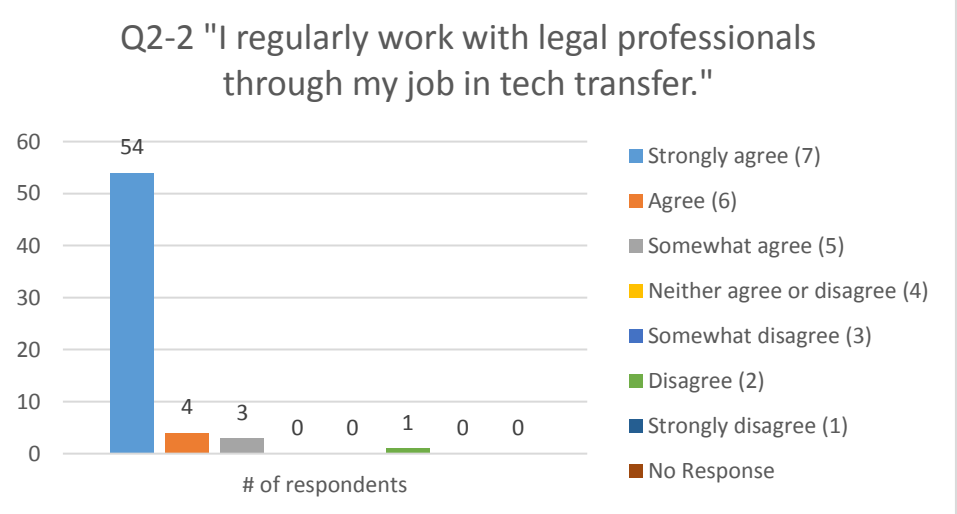
Answer	%	Count
Extremely knowledgeable (5)	21.92%	16
Very knowledgeable (4)	49.32%	36
Moderately knowledgeable (3)	21.92%	16
Slightly knowledgeable (2)	4.11%	3
Not knowledgeable at all (1)	2.74%	2
Total	100%	73

NOTE: "Not knowledgeable at all" for Q1 and/or Q3 removed from all other data analysis

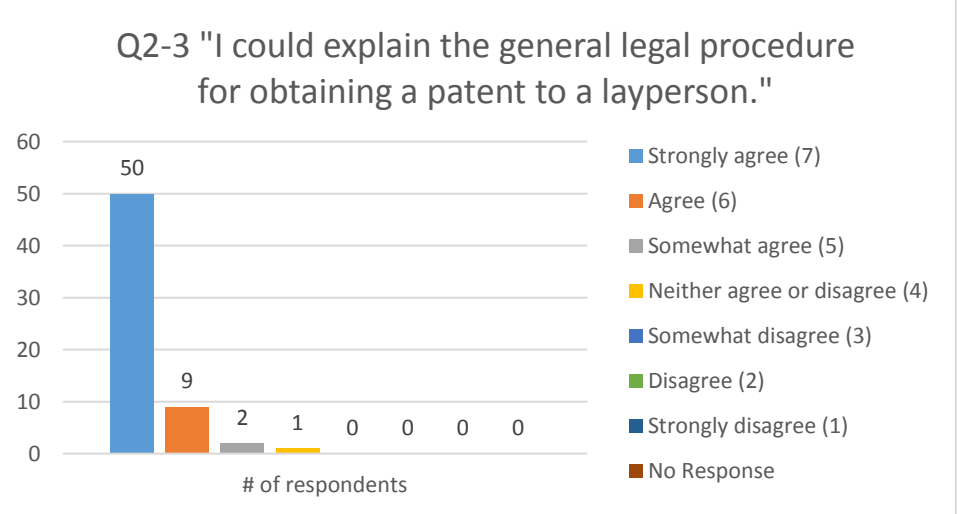
Q2 - Please rate your agreement with the following statements:



Mean	6.18
Std. Deviation	0.93
Variance	0.87
Response #	62



Mean	6.76
Std. Deviation	0.78
Variance	0.61
Response #	62



Mean	6.74
Std. Deviation	0.60
Variance	0.36
Response #	62

DEMOGRAPHICS: UNDERSTANDING OF U.S. PATENTING

Q2_1

Shapiro-Wilk normality test (Q2_1): p-value = 1.454e-08

95% CI ($\alpha = 0.05$), H_0 = Normality

p-value < α, so reject null hypothesis

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test ($H_0 : D = 0 \rightarrow$ no difference), $\alpha = 0.05$ (95% CI)

Question: Does the data support that respondents agree to having a confident understanding of U.S. patenting?

p-value < 2.2e-16 (p-value < α, so reject H_0)

95% CI is $D \in (5.940597, 6.414242)$

t = 52.159, df = 61

mean = 6.177419, sd = 0.932548, variance = 0.8696457

Conclusion: Data supports that respondents agree to having a confident understanding of U.S. patenting.

LIKERT SCALE:

STRONGLY AGREE (7)
AGREE (6)
SOMEWHAT AGREE (5)
NEITHER AGREE NOR DISAGREE (4)
SOMEWHAT DISAGREE (3)
DISAGREE (2)
STRONGLY DISAGREE (1)

Q2_2

Shapiro-Wilk normality test (Q2_2): p-value = 4.708e-15

95% CI ($\alpha = 0.05$) → p-value < α, so reject null hypothesis (Normality)

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test ($H_0 : D = 0 \rightarrow$ no difference), $\alpha = 0.05$ (95% CI)

Question: Does the data support that respondents agree to working regularly with legal professionals?

p-value < 2.2e-16 (p-value < α, so reject H_0)

95% CI is $D \in (6.559293, 6.956836)$

t = 67.985, df = 61

mean = 6.758065, sd = 0.7827125, variance = 0.6126388

Conclusion: Data supports that respondents agree to working regularly with legal professionals.

Q2_3

Shapiro-Wilk normality test (Q2_3): p-value = 2.597e-13 (p-value < α (α = 0.05)); not Normally distributed

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test ($H_0 : D = 0 \rightarrow$ no difference), $\alpha = 0.05$ (95% CI)

Question: Does the data support that respondents agree to being able to explain patenting to a layperson?

p-value < 2.2e-16 (p-value < α, so reject H_0)

95% CI is $D \in (6.589873, 6.893998)$

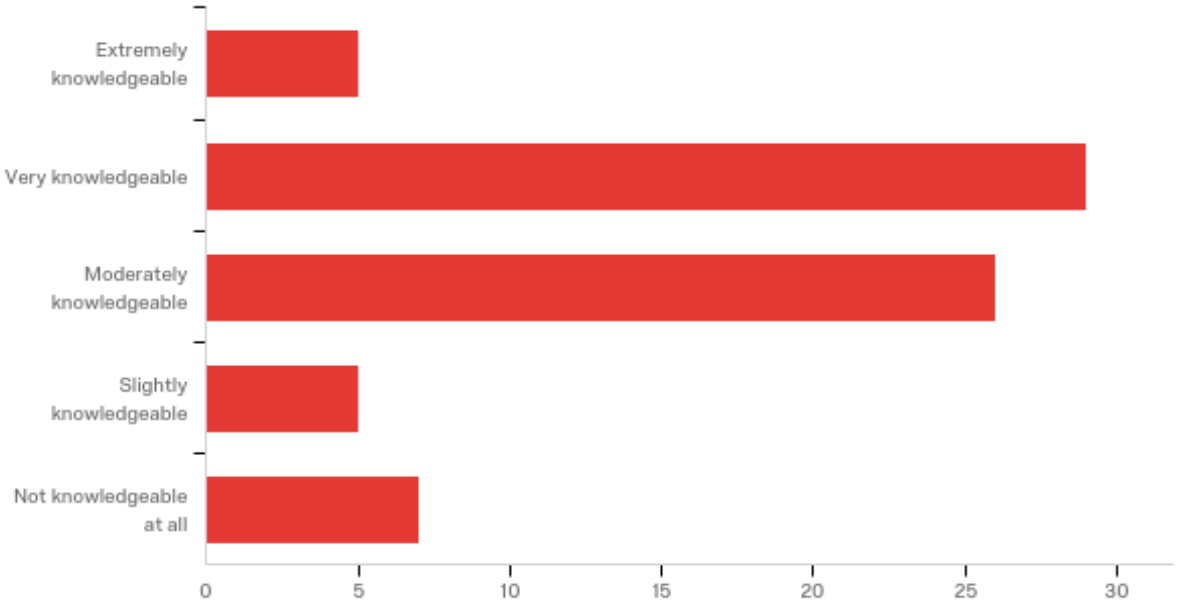
t = 88.657, df = 61

mean = 6.741935, sd = 0.5987825, variance = 0.3585405

Conclusion: Data supports that respondents agree to being able to explain patenting to a layperson.

QUESTION PURPOSE:
IDENTIFY AND REMOVE RESPONDENTS WITH LOW FAMILIARITY

Q3 - Please rank your familiarity with Association for Molecular Pathology v. Myriad Genetics, Inc. (U.S. Supreme Court, 2013) compared to other tech transfer professionals:

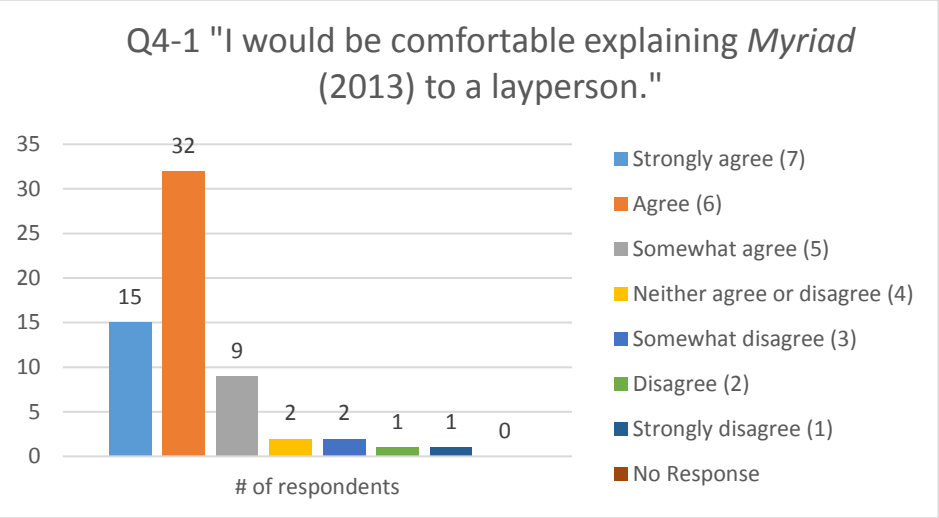


Minimum	Maximum	Mean	Std Deviation	Variance	Count
1.00	5.00	2.72	1.03	1.06	72

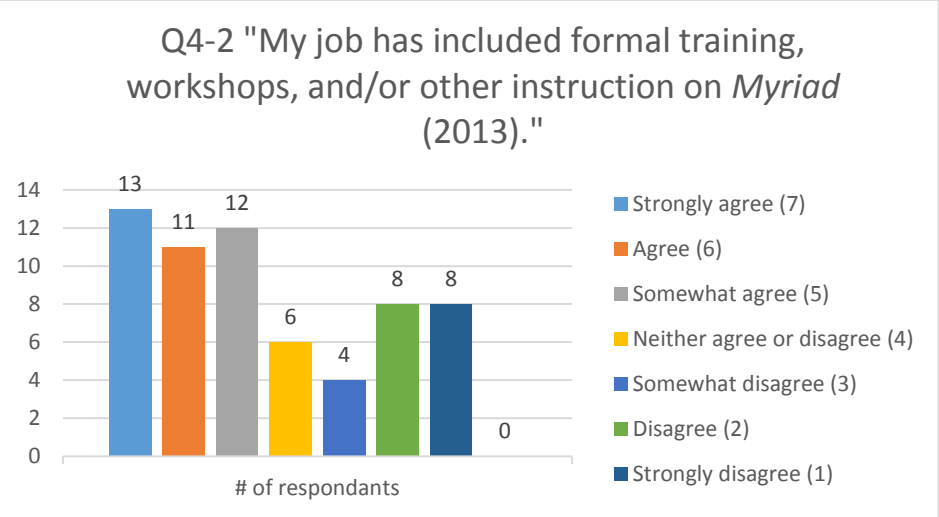
Answer	%	Count
Extremely knowledgeable (5)	6.94%	5
Very knowledgeable (4)	40.28%	29
Moderately knowledgeable (3)	36.11%	26
Slightly knowledgeable (2)	6.94%	5
Not knowledgeable at all (1)	9.72%	7
Total	100%	72

NOTE: "Not knowledgeable at all" for Q1 and/or Q3 removed from all other data analysis

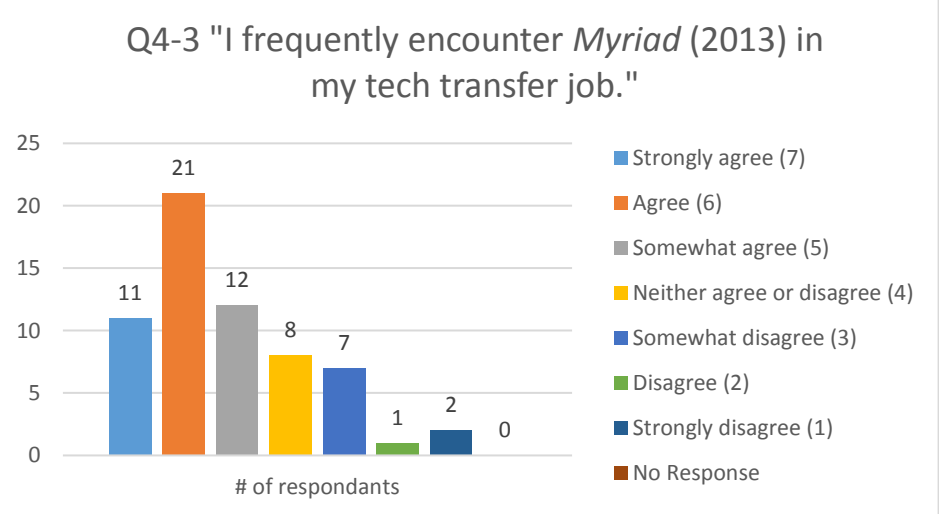
Q4 - Please rate your agreement with the following statements:



Mean	5.79
Std. Deviation	1.20
Variance	1.45
Response #	62



Mean	4.47
Std. Deviation	2.09
Variance	4.38
Response #	62



Mean	5.16
Std. Deviation	1.52
Variance	2.30
Response #	62

DEMOGRAPHICS: UNDERSTANDING OF *MYRIAD* CASE

Q4_1

Shapiro-Wilk normality test (Q4_1): p-value = 8.261e-09

95% CI ($\alpha = 0.05$), H_0 = Normality

p-value < α, so reject null hypothesis

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test ($H_0 : D = 0 \rightarrow$ no difference), $\alpha = 0.05$ (95% CI)

Question: Does the data support that respondents agree to being comfortable explaining *Myriad* to a layperson?

p-value < 2.2e-16 (p-value < α, so reject H_0)

95% CI is $D \in (5.484827, 6.095818)$

t = 37.901, df = 61

mean = 5.790323, sd = 1.202962, variance = 1.447118

Conclusion: Data supports that respondents agree to being comfortable explaining *Myriad* to a layperson.

LIKERT SCALE:

STRONGLY AGREE (7)
AGREE (6)
SOMEWHAT AGREE (5)
NEITHER AGREE NOR DISAGREE (4)
SOMEWHAT DISAGREE (3)
DISAGREE (2)
STRONGLY DISAGREE (1)

Q4_2

Shapiro-Wilk normality test (Q4_2): p-value = 3.038e-05

95% CI ($\alpha = 0.05$) → p-value < α, so reject null hypothesis (Normality)

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test ($H_0 : D = 0 \rightarrow$ no difference), $\alpha = 0.05$ (95% CI)

Question: Does the data support that respondents agree to having had formal job training on *Myriad*?

p-value < 2.2e-16 (p-value < α, so reject H_0)

95% CI is $D \in (3.936005, 4.999479)$

t = 16.801, df = 61

mean = 4.467742, sd = 2.093845, variance = 4.384188

Conclusion: Data supports that respondents agree to having had formal job training on *Myriad*.

Q4_3

Shapiro-Wilk normality test (Q4_3): p-value = 4.694e-05 (p-value < α ($\alpha = 0.05$)); not Normally distributed

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test ($H_0 : D = 0 \rightarrow$ no difference), $\alpha = 0.05$ (95% CI)

Question: Does the data support that respondents agree to frequently encountering *Myriad* in their job?

p-value < 2.2e-16 (p-value < α, so reject H_0)

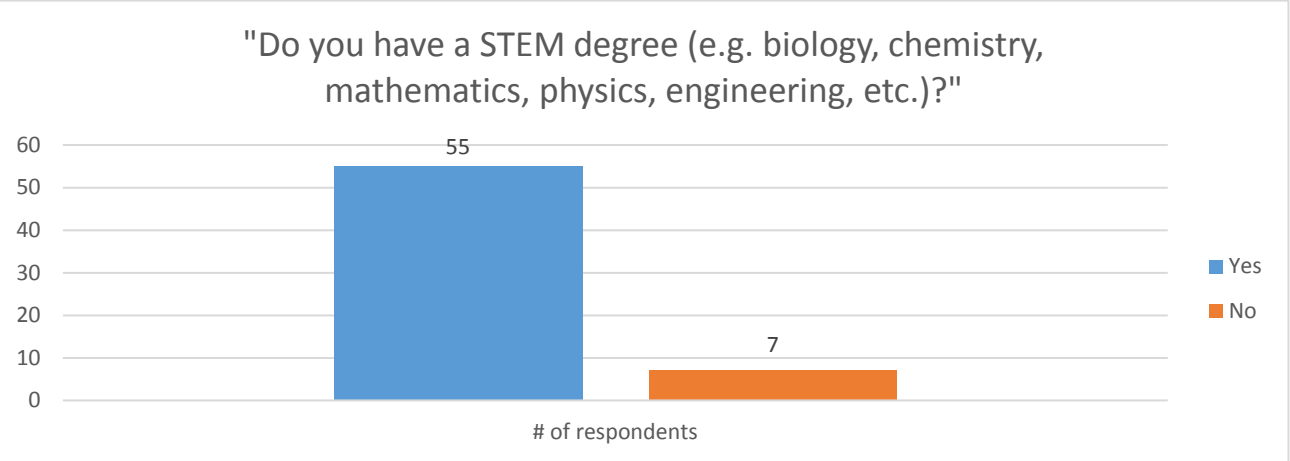
95% CI is $D \in (4.776033, 5.546548)$

t = 26.789, df = 61

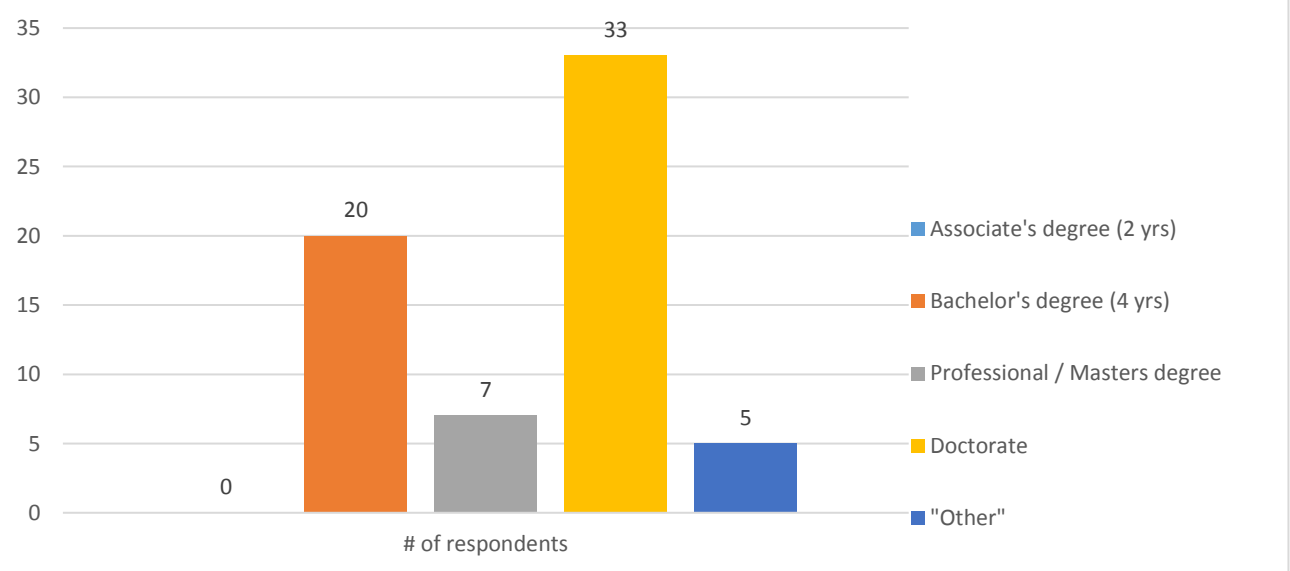
mean = 5.16129, sd = 1.517046, variance = 2.301428

Conclusion: Data supports that respondents agree to frequently encountering *Myriad* in their job.

Q5 - Do you have a STEM degree (e.g. biology, chemistry, mathematics, physics, engineering, etc.)?



Q6 - If you responded "Yes" to the previous question, what degree(s) have you completed in a STEM field? (Please select all that apply).

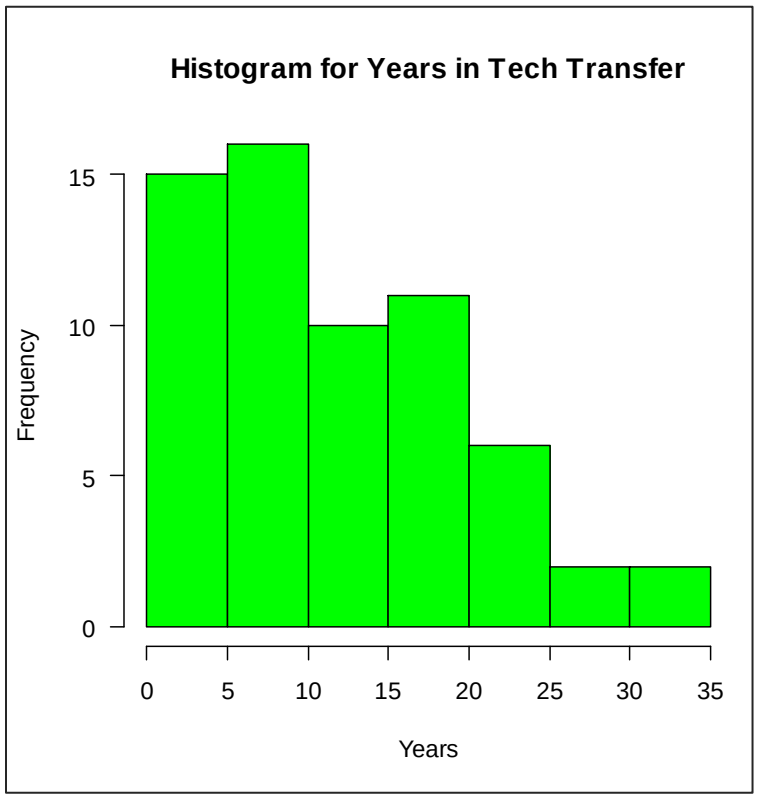


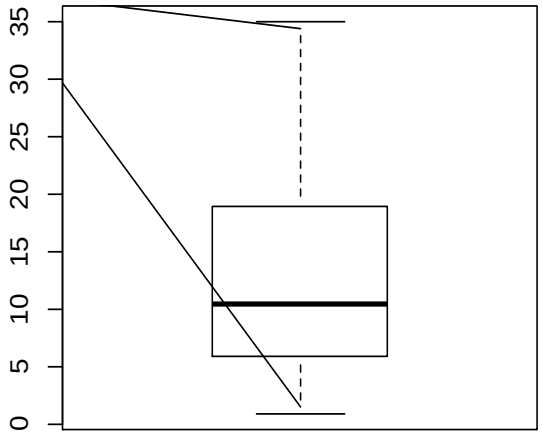
Other - Text

MS , Masters, JD, Master's Degree, Masters, Master of Science

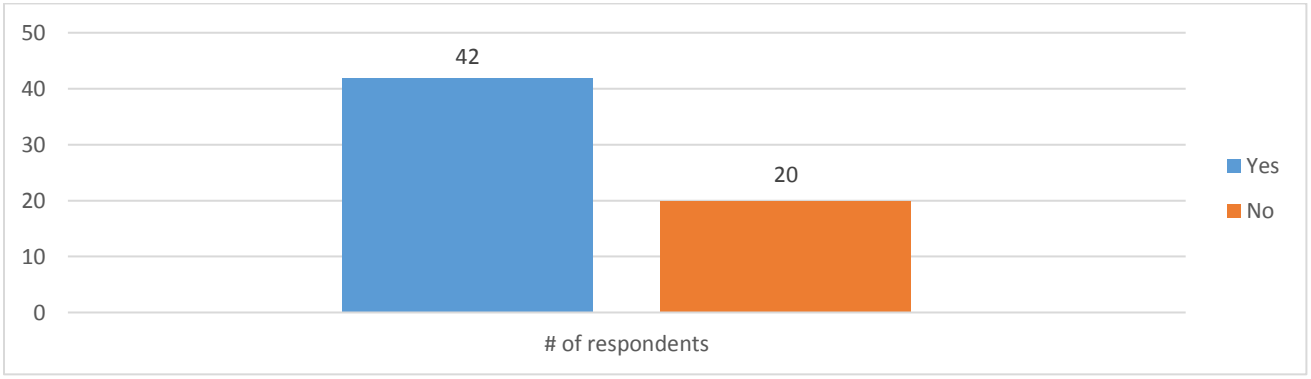
Q7 - Approximately how many years in total have you worked in technology transfer?

Minimum	Maximum	Mean	Median	Std Deviation	Variance	Count
1.00	35.00	12.47	10.5	8.40	70.59	62





Q8 - Were you working within the field of technology transfer before the *Myriad* court decision (prior to 2013)?

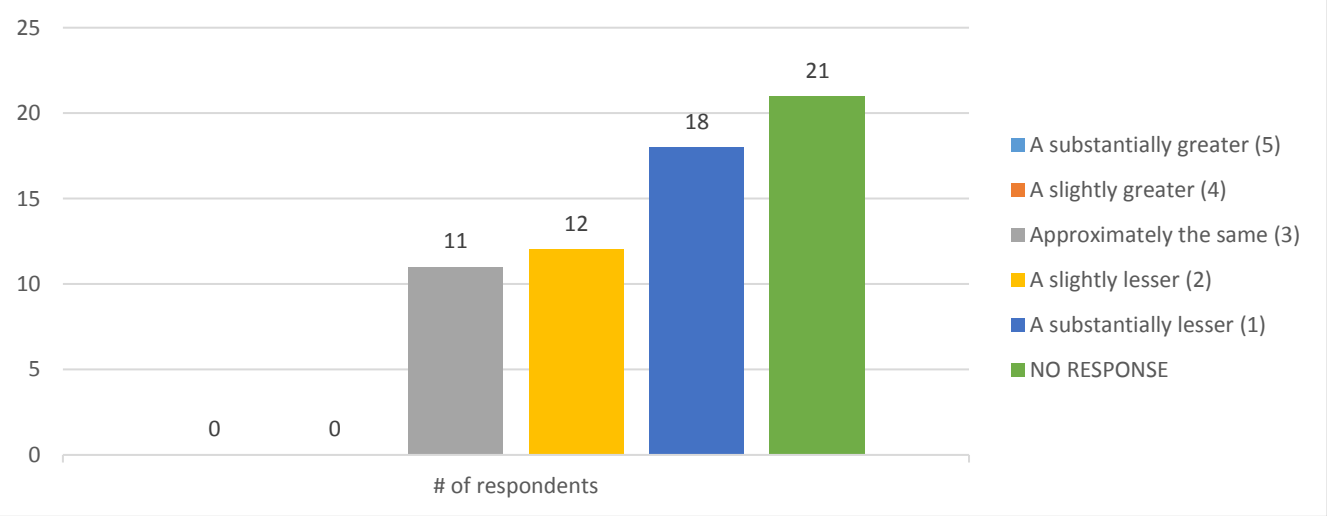


Note: Question 9 below was only shown to respondents who responded "yes" to the prior question (Question 8), affirming that they were working in technology transfer before the *Myriad* decision.

MEASURING: PATENTING BEHAVIORS POST-*MYRIAD*

Q9 – Since the *Myriad* (2013) ruling, my university of employment has pursued _____ number of natural product patents than before *Myriad*.

Note: "natural product" is defined as a substance produced by life, found in or derived from nature (e.g. nucleic acids, foods, bacteria, proteins and peptides, chemicals from natural sources including antibiotics and resins)



Q9

Shapiro-Wilk normality test (Q9): p-value = 1.581e-06

95% CI ($\alpha = 0.05$), H_0 = Normality

p-value < α, so reject null hypothesis

Histogram Overlay: bell curve, sufficient sample size > 30 (41)

t-test ($H_0 : D = 0 \rightarrow$ no difference), $\alpha = 0.05$ (95% CI)

Question: Does the data support that respondents agree to their university pursuing a lesser number of natural product patents post-*Myriad*?

p-value < 2.2e-16 (p-value < α, so reject H_0)

95% CI is $D \in (1.566108, 2.092429)$

t = 14.049, df = 40

mean = 1.829268, sd = NA, variance = NA

Conclusion: Data supports that respondents agree to their university pursuing a lesser number of natural product patents post-*Myriad*?

LIKERT SCALE:

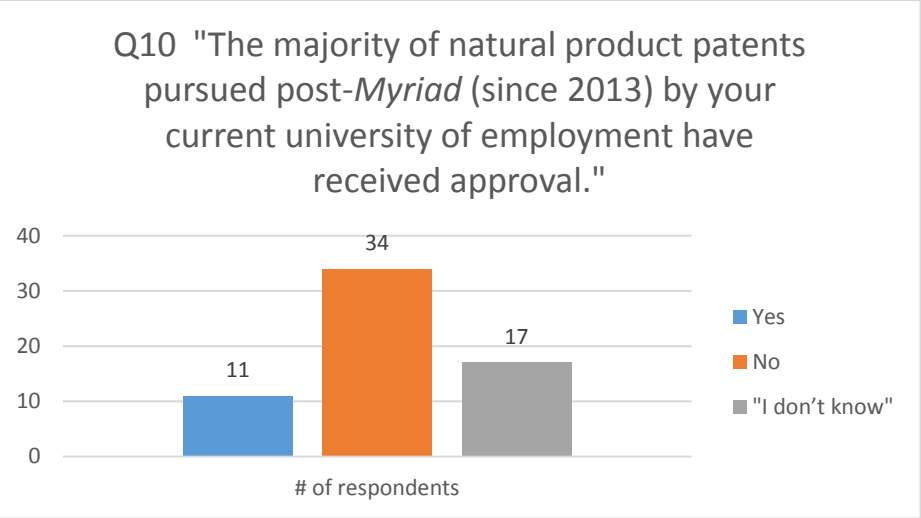
(5) SUBSTANTIALLY GREATER #

(4) SLIGHTLY GREATER #

(3) APPROX THE SAME #

(2) SLIGHTLY LESSER # STRONGLY

(1) SUBSTANTIALLY LESSER #



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.755556
t-value	27.097
df	44
p-value	<2.2e-16
95% CI	(1.624983, 1.886128)
Std Dev/ Var.	NA
Response #	45

Q10

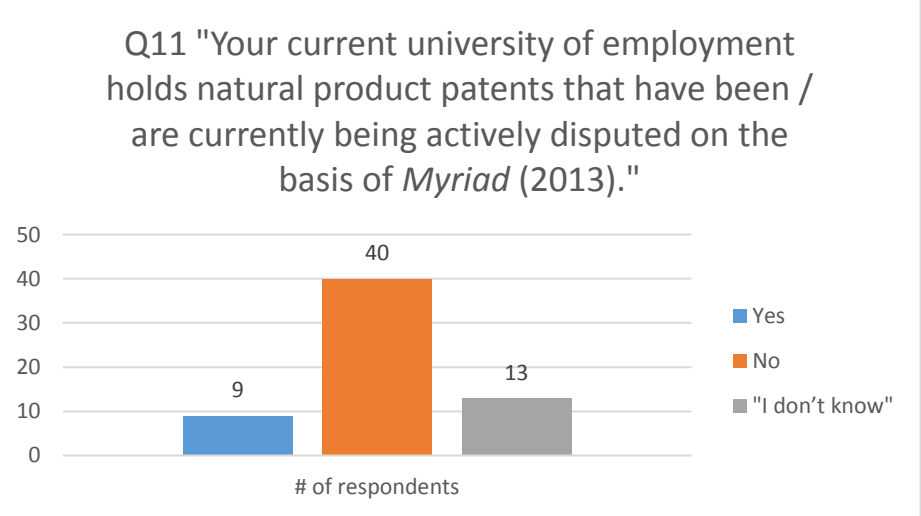
Shapiro-Wilk normality test (Q10): p-value = 9.674e-11 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (45)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of n.p. patents pursued post-Myriad were approved?

Conclusion: No, the data supports that the majority of n.p. patents pursued post-Myriad were not approved.



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.816327
t-value	32.498
df	48
p-value	<2.2e-16
95% CI	(1.703952, 1.928701)
Std Dev/ Var.	NA
Response #	49

Q11

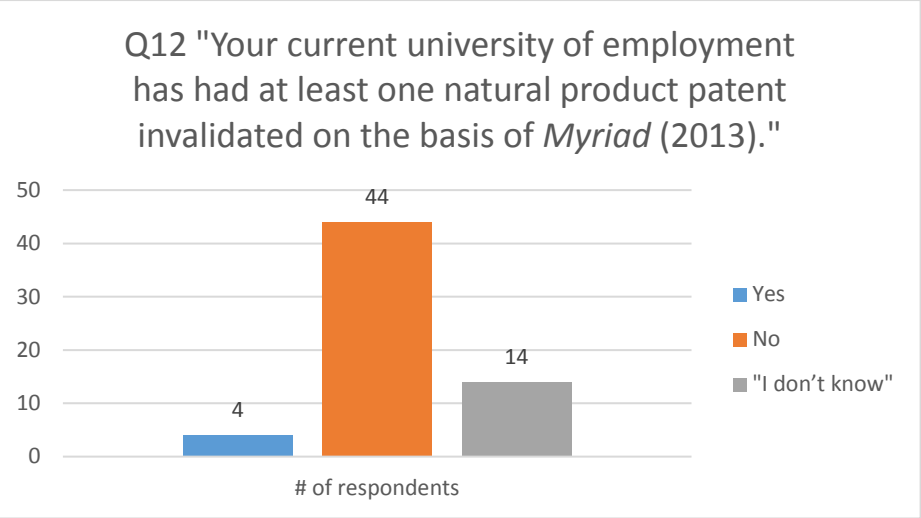
Shapiro-Wilk normality test (Q11): p-value = 4.885e-12 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (49)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of n.p. patents held post-*Myriad* are/have been disputed?

Conclusion: The data supports that the majority of n.p. patents held post-Myriad aren't/haven't been disputed



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.916667
t-value	47.542
df	47
p-value	<2.2e-16
95% CI	(1.835563, 1.997770)
Std Dev/ Var.	NA
Response #	48

Q12

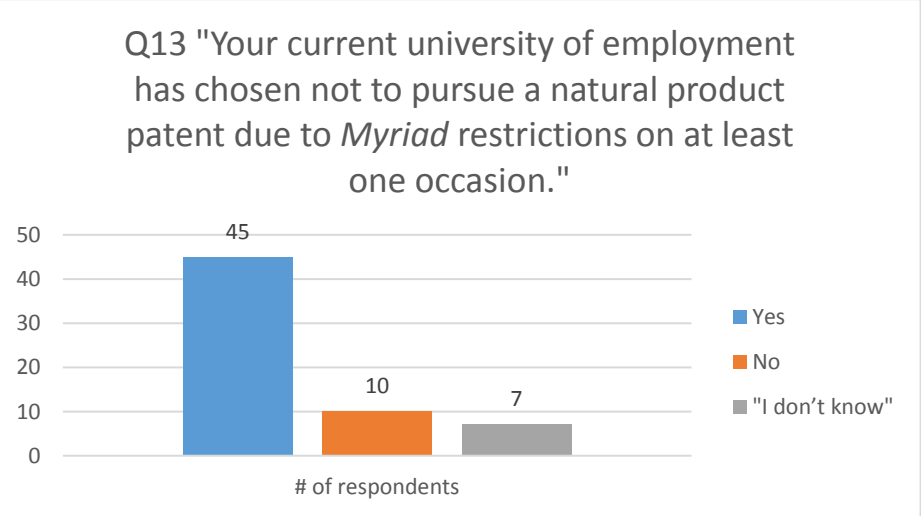
Shapiro-Wilk normality test (Q12): p-value = 1.11e-13 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (48)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the maj. of resp. have had at least one n.p. patent invalidated by *Myriad*?

Conclusion: The data supports that the majority of respondents haven't had at least one n.p. patent invalidated.



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.181818
t-value	22.517
df	54
p-value	<2.2e-16
95% CI	(1.076589, 1.287047)
Std Dev/ Var.	NA
Response #	55

Q13

Shapiro-Wilk normality test (Q12): p-value = 8.206e-13 (p-value < α (α = 0.05))

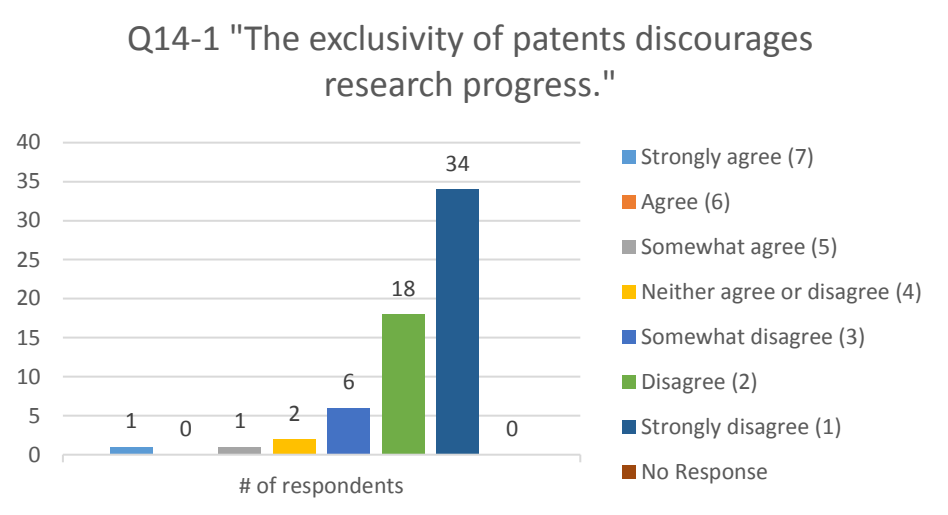
Histogram Overlay: bell curve, sufficient sample size > 30 (55)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Q: Does the data support that the majority of resp. have chosen not to pursue a n.p. patent due to *Myriad*?

Conclusion: Yes, the data supports that the majority of respondents have chosen not to pursue a n.p. patent due to *Myriad* on at least one occasion.

Q14 - Please rate your agreement with the following statements:



Mean	1.741935
t-value	12.14
df	61
p-value	<2.2e-16
95% CI	(1.455006, 2.028865)
Std Deviation	1.129855
Variance	1.276573
Response #	62

Q14_1

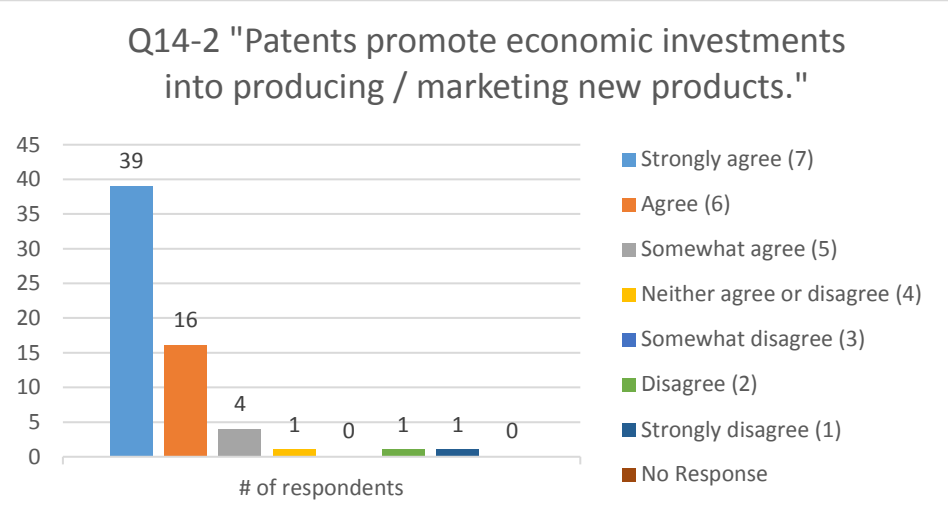
Shapiro-Wilk normality test (Q14-1): p-value = 2.224e-10 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents agree with the statement in Q14-1?

Conclusion: No, the data supports that the majority of respondents do not agree with the statement in Q14-1.



Mean	6.387097
t-value	44.274
df	61
p-value	<2.2e-16
95% CI	(6.098626, 6.675567)
Std Deviation	1.135924
Variance	1.290323
Response #	62

Q14_2

Shapiro-Wilk normality test (Q14-2): p-value = 4.865e-12 (p-value < α (α = 0.05))

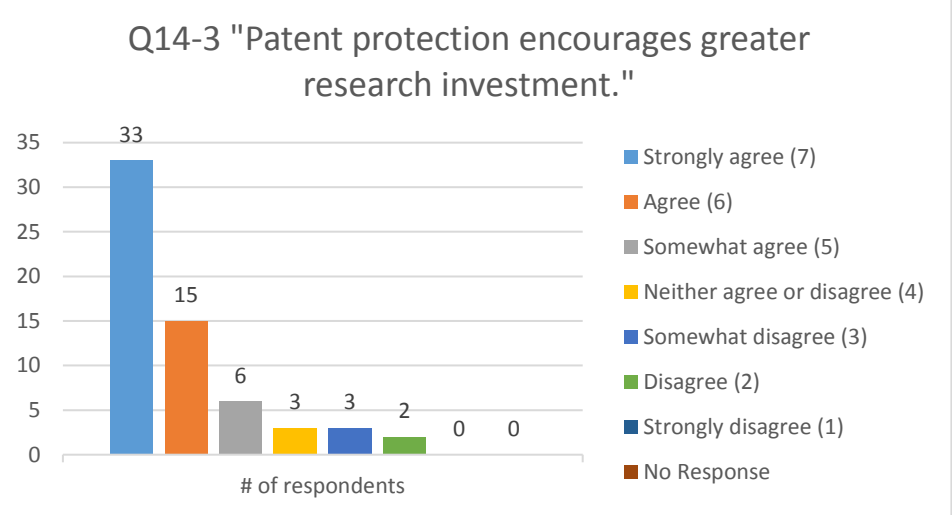
Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents agree with the statement in Q14-2?

Conclusion: Yes, the data supports that the majority of respondents agree with the statement in Q14-2.

Q14 (cont.)- Please rate your agreement with the following statements:



Mean	6.064516
t-value	35.602
df	61
p-value	<2.2e-16
95% CI	(5.723893, 6.405139)
Std Deviation	1.341286
Variance	1.799048
Response #	62

Q14_3

Shapiro-Wilk normality test (Q14_3): p-value = 1.74e-09 (p-value < α (α = 0.05))

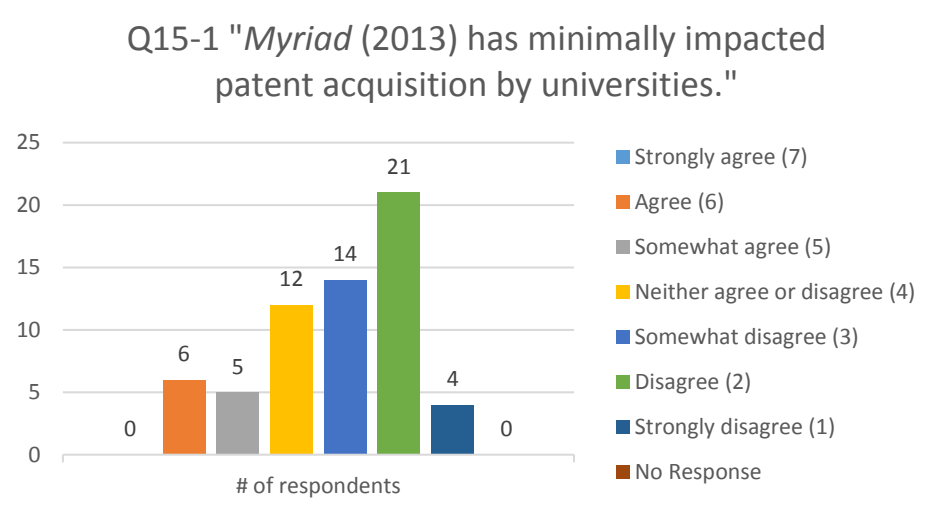
Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents agree with the statement in Q14-3?

Conclusion: Yes, the data supports that the majority of respondents agree with the statement in Q14-3.

Q15 - Please rate your agreement with the following statements:



Mean	3.177419
t-value	17.761
df	61
p-value	<2.2e-16
95% CI	(2.819680, 3.535159)
Std Deviation	1.408687
Variance	1.9844
Response #	62

Q15_1

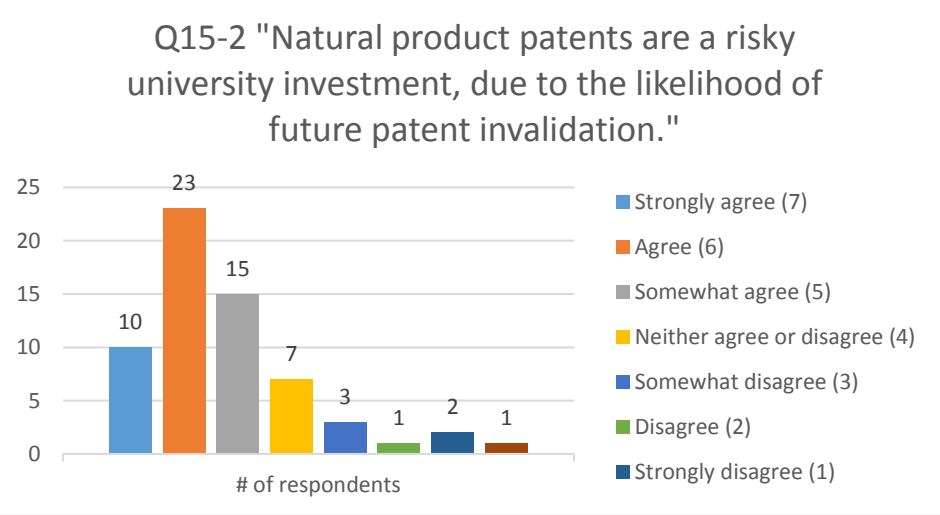
Shapiro-Wilk normality test (Q15-1): p-value = 7.829e-05 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents agree with the statement in Q15-1?

Conclusion: No, the data supports that the majority of respondents disagree with the statement in Q15-1.



Mean	5.311475
t-value	29.697
df ("No Resp." removed)	60
p-value	<2.2e-16
95% CI	(4.953709, 5.669241)
Std Deviation	1.39
Variance	1.96
Response #	61

Q15_2

Shapiro-Wilk normality test (Q15-2): p-value = 5.381e-06 (p-value < α (α = 0.05))

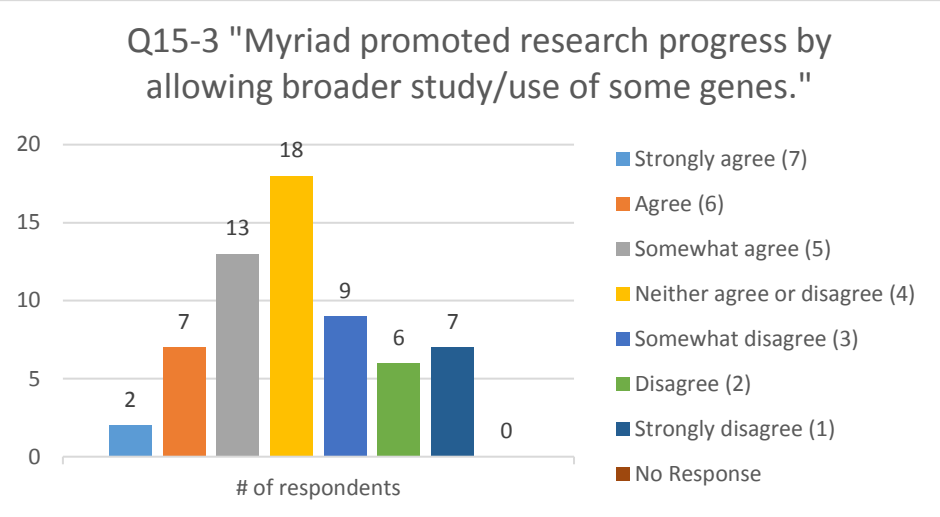
Histogram Overlay: bell curve, sufficient sample size > 30 (61)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents agree with the statement in Q15-2?

Conclusion: Yes, the data supports that the majority of respondents agree with the statement in Q15-2.

Q15 (cont.) - Please rate your agreement with the following statements:



Mean	3.854839
t-value	19.122
df	61
p-value	<2.2e-16
95% CI	(3.451736, 4.257941)
Std Deviation	1.587314
Variance	2.519566
Response #	62

Q15_3

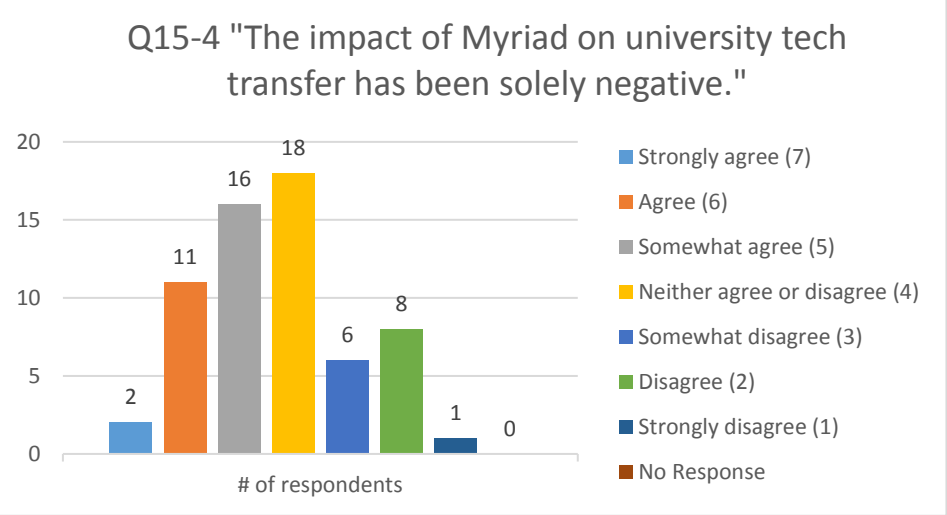
Shapiro-Wilk normality test (Q15_3): p-value = 0.004014 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents agree with the statement in Q15-3?

Conclusion: No, the data supports that respondents are split pretty evenly, with a slight majority disagreeing.



Mean	4.306452
t-value	24.26
df	61
p-value	<2.2e-16
95% CI	(3.951487, 4.661416)
Std Deviation	1.397758
Variance	1.953728
Response #	62

Q15_4

Shapiro-Wilk normality test (Q15_4): p-value = 0.00264 (p-value < α (α = 0.05))

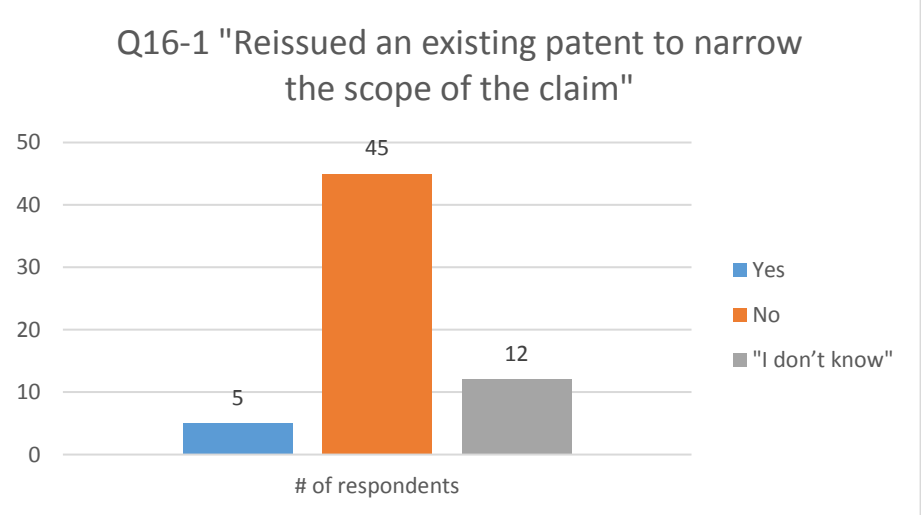
Histogram Overlay: bell curve, sufficient sample size > 30 (62)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents agree with the statement in Q15-4?

Conclusion: No, the data supports that respondents are split pretty evenly, with a slight majority agreeing.

Q16 - To your knowledge, have any of these strategies been used at your current university of employment in a natural product patent application post-Myriad (since 2013)?



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.9
t-value	44.333
df	49
p-value	<2.2e-16
95% CI	(1.813875, 1.986125)
Std Dev/ Var.	NA
Response #	62

Q16_1

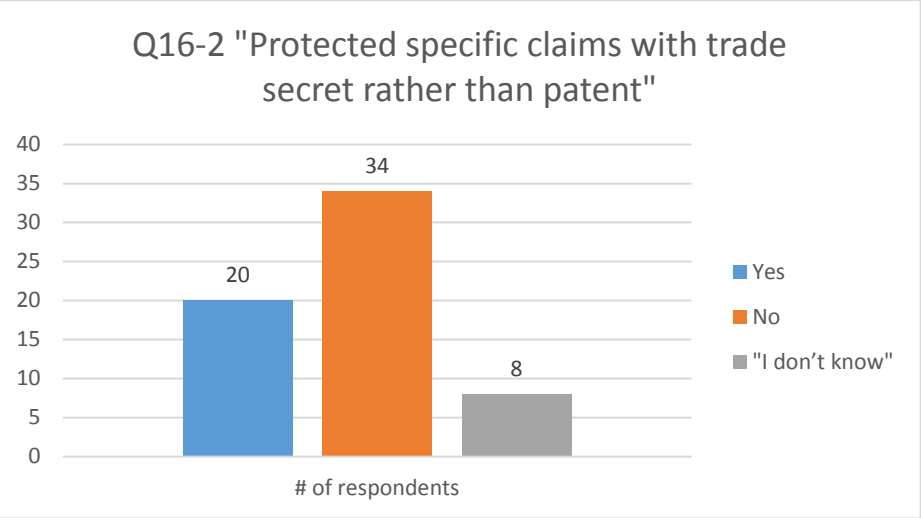
Shapiro-Wilk normality test (Q16_1): p-value = 1.3e-13 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (50)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents have used the strategy in Q16-1?

Conclusion: No, the data supports that the majority of respondents have not used the strategy in Q16-1.



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.62963
t-value	24.568
df	53
p-value	<2.2e-16
95% CI	(1.496585, 1.762675)
Std Dev/ Var.	NA
Response #	54

Q16_2

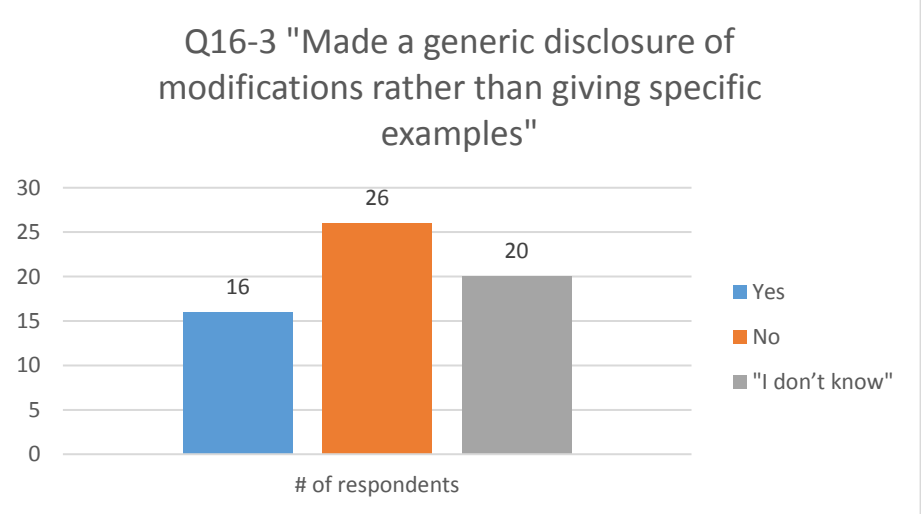
Shapiro-Wilk normality test (Q16-2): p-value = 1.059e-10 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (54)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents have used the strategy in Q16-2?

Conclusion: The data supports that respondents who have not used this strategy constitute a small majority..



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.619048
t-value	21.348
df	41
p-value	<2.2e-16
95% CI	(1.465883, 1.772212)
Std Dev/ Var.	NA
Response #	42

Q16_3

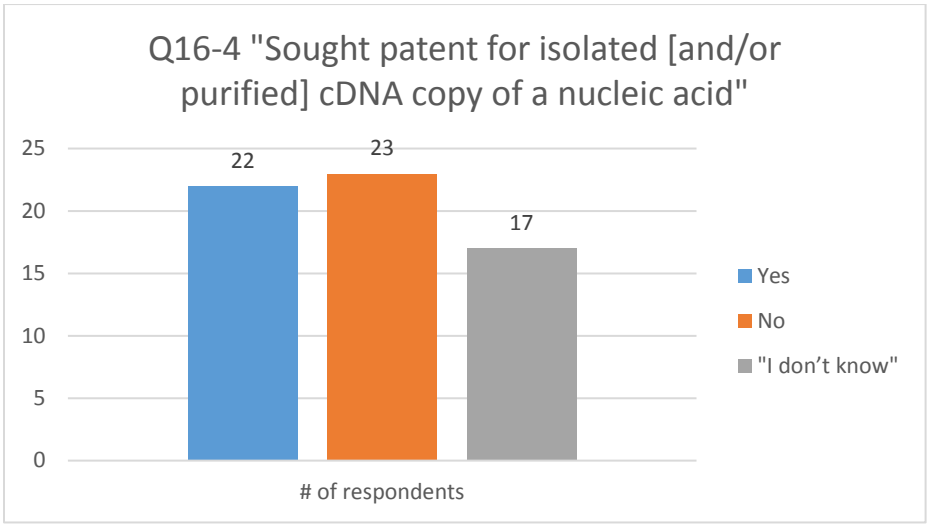
Shapiro-Wilk normality test (Q16-3): p-value = 2.961e-09 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (42)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents have used the strategy in Q16-3?

Conclusion: The data supports that the respondents who have not used this strategy constitute a small majority.



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.511111
t-value	20.052
df	44
p-value	<2.2e-16
95% CI	(1.359235, 1.662988)
Std Dev/ Var.	NA
Response #	45

Q16_4

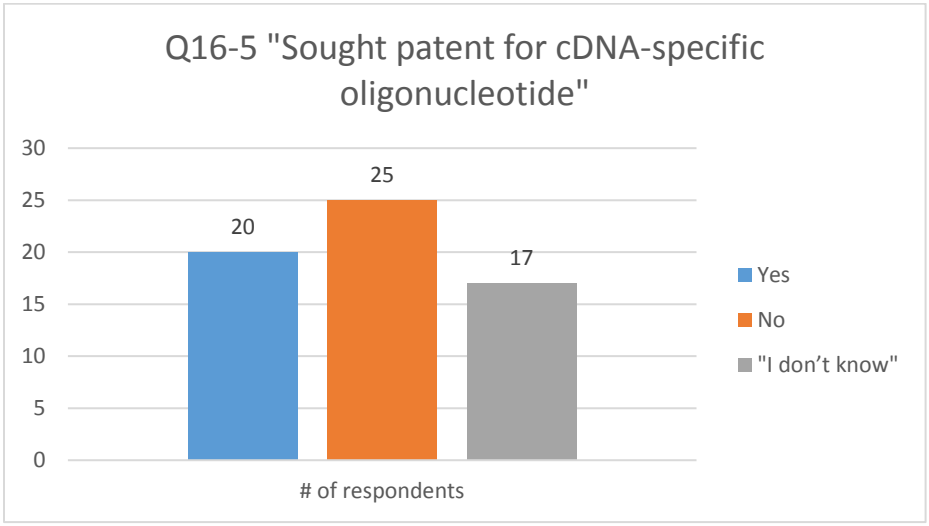
Shapiro-Wilk normality test (Q16-4): p-value = 2.616e-09 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (45)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents have used the strategy in Q16-4?

Conclusion: No, the data supports that the respondents are split pretty evenly over the strategy in Q16-4.



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.555556
t-value	20.765
df	44
p-value	<2.2e-16
95% CI	(1.404582, 1.706529)
Std Dev/ Var.	NA
Response #	45

Q16_5

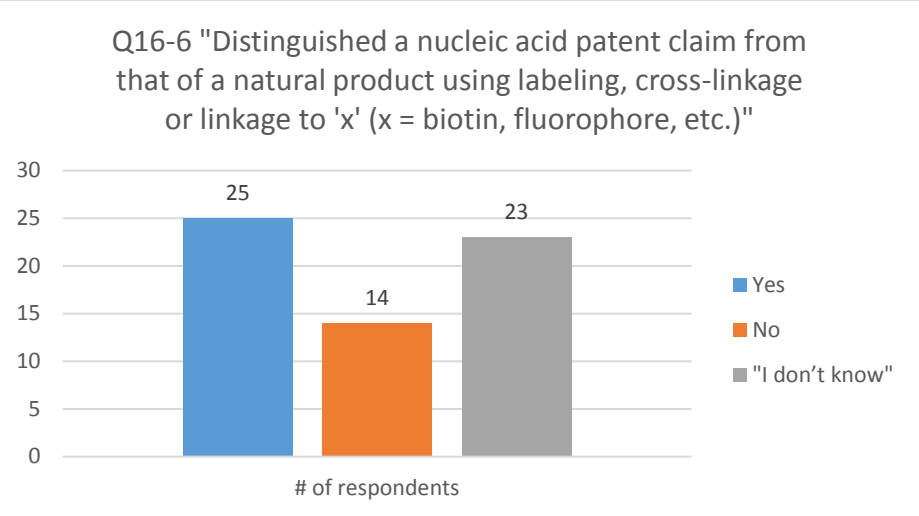
Shapiro-Wilk normality test (Q16_5): p-value = 2.25e-09 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (45)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents have used the strategy in Q16-5?

Conclusion: No, the data supports that the respondents are split pretty evenly over the strategy in Q16-5.



"I don't know" removed from t-test analysis Yes = 1, No = 2	
Mean	1.358974
t-value	17.464
df	38
p-value	<2.2e-16
95% CI	(1.201441, 1.516508)
Std Dev/ Var.	NA
Response #	39

Q16_6

Shapiro-Wilk normality test (Q16-5): p-value = 5.366e-09 (p-value < α (α = 0.05))

Histogram Overlay: bell curve, sufficient sample size > 30 (39)

t-test (H_0 : D = 0 → no difference), α = 0.05 (95% CI)

Question: Does the data support that the majority of respondents have used the strategy in Q16-6?

Conclusion: Yes, the data supports that the majority of respondents have used the strategy in Q16-6.

Q17 - In your own opinion, have those strategies to which you responded "yes" above been generally successful in protecting existing patents of your university and/or in obtaining new patents?

PROBLEMS WITH Q17 DATA (THREE FOLLOWING PAGES)

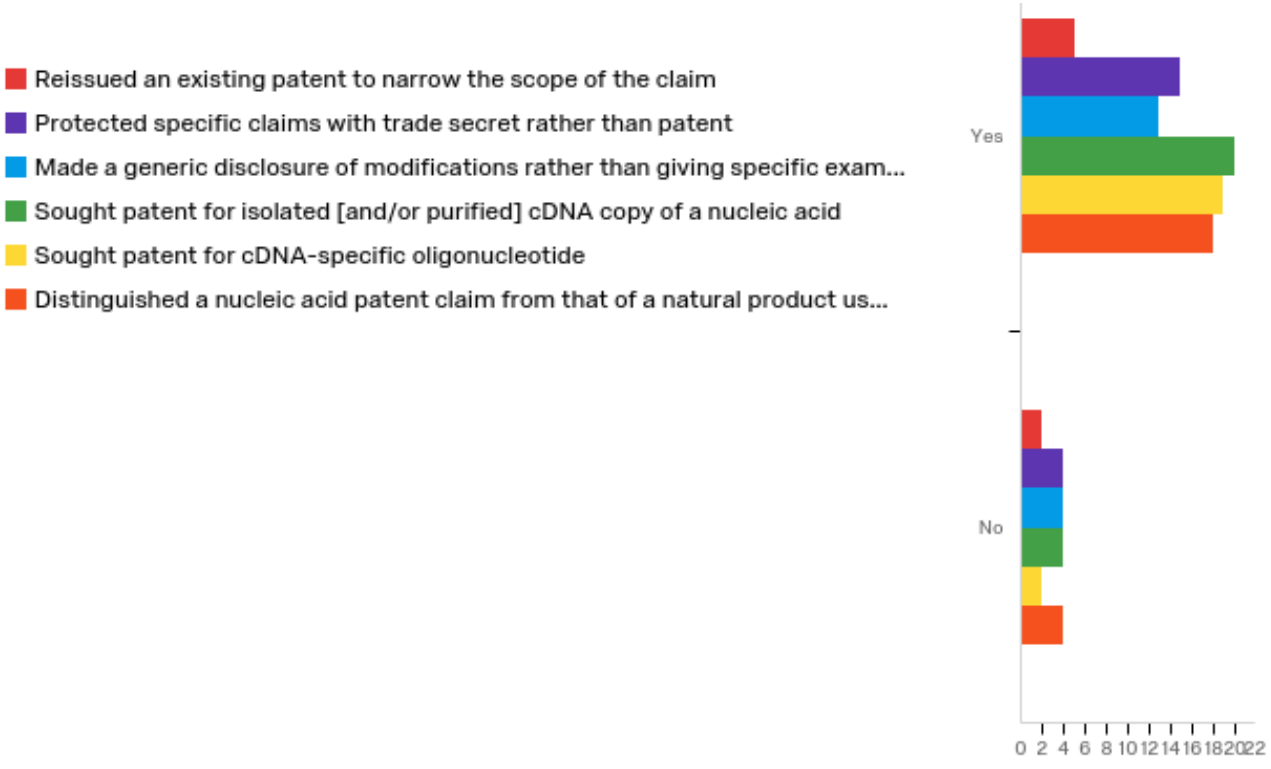
RESPONSE CONFUSION → POSSIBLY A RESULT OF SURVEY SETUP

More respondents ended up answering this question than just those who responded "yes" to strategies in Question 16. Therefore, at least some respondents in this section would have answered without having used the strategy themselves at their current university of employment.

INSUFFICIENT SAMPLE SIZE FOR STATISTICALLY SIGNIFICANT ANALYSIS

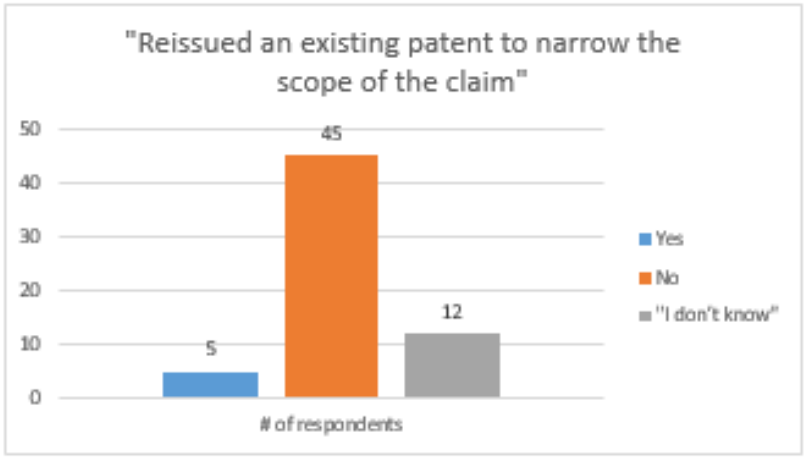
The Shapiro-Wilk normality test for each of the following questions revealed that the data was not Normally distributed. The Central Limit Theorem would have allowed for a student's t-test still if the data sets were "sufficiently large" (generally agreed to be n > 30 for data demonstrating a mound-shaped / bell curve histogram overlay). However, the data sets did not meet this size requirement either.

"For practitioners, the histogram (for shape) and the sample size are more important than the Shapiro-Wilk test." – Dr. Ole Forsberg, Ph.D. Statistics

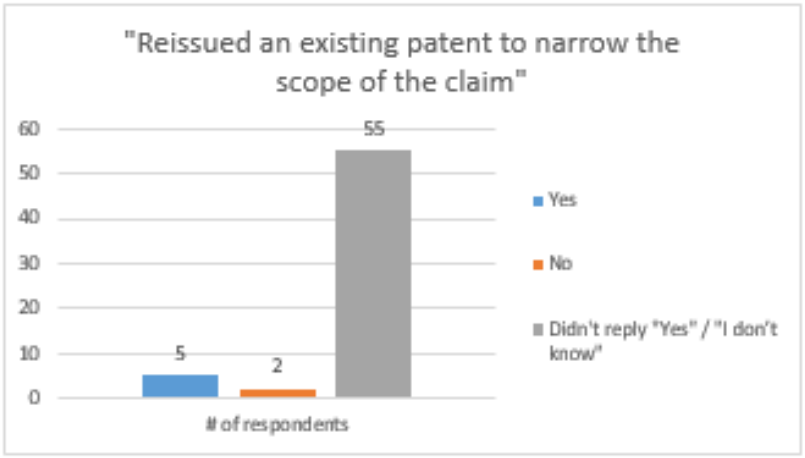


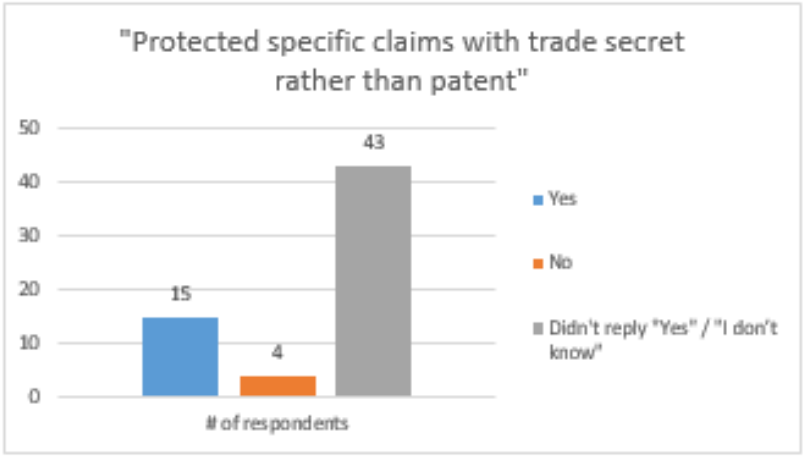
PATENTING STRATEGIES / RESPONSES

"To your knowledge, have any of these strategies been used at **your current university of employment** in a natural product patent application post-Myriad (since 2013)"



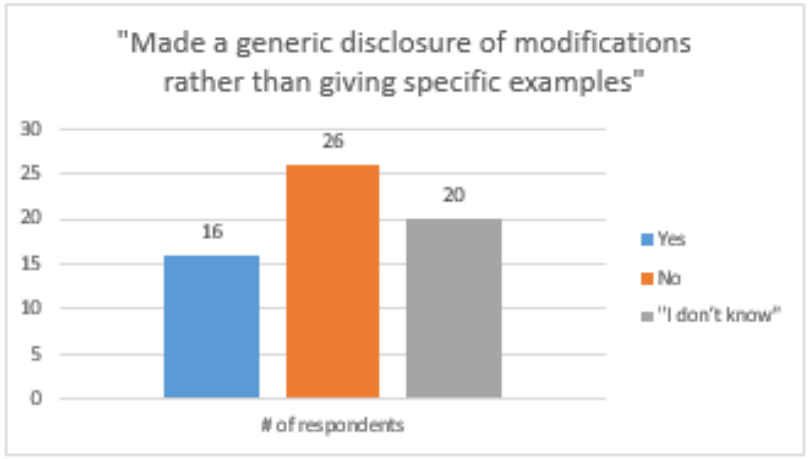
"In your own opinion, have those strategies **to which you responded "yes"** been generally successful in protecting existing patents of your university / obtaining new patents?"

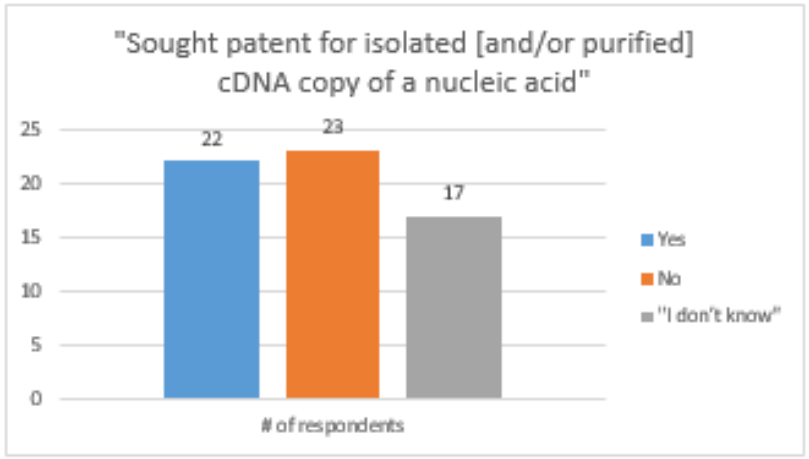




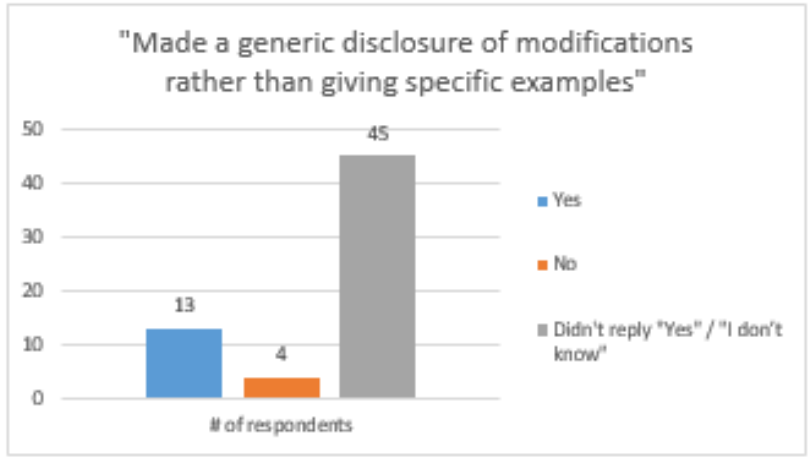
PATENTING STRATEGIES / RESPONSES, CONT. (1)

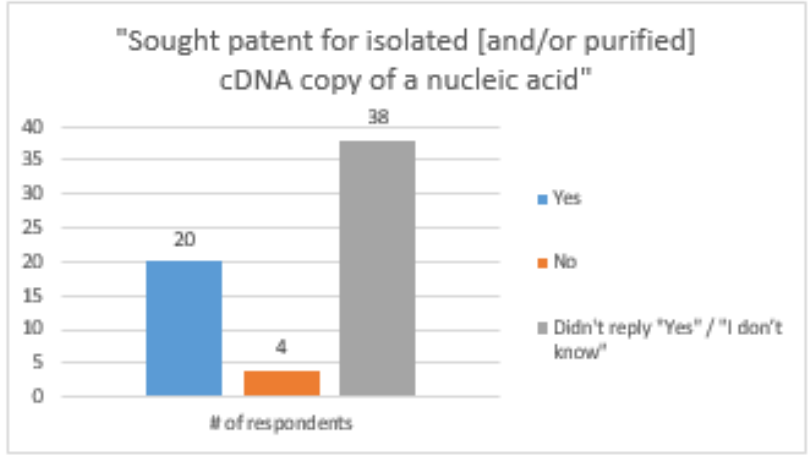
"To your knowledge, have any of these strategies been used at **your current university of employment** in a natural product patent application post-Myriad (since 2013)"





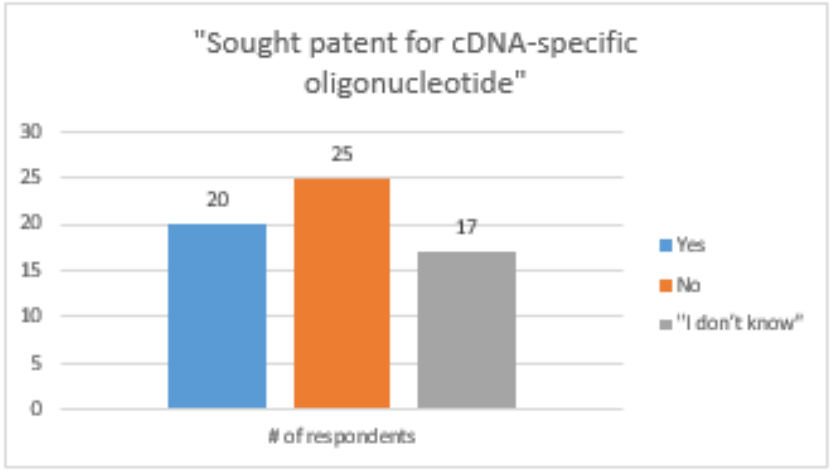
"In your own opinion, have those strategies **to which you responded "yes"** been generally successful in protecting existing patents of your university / obtaining new patents?"

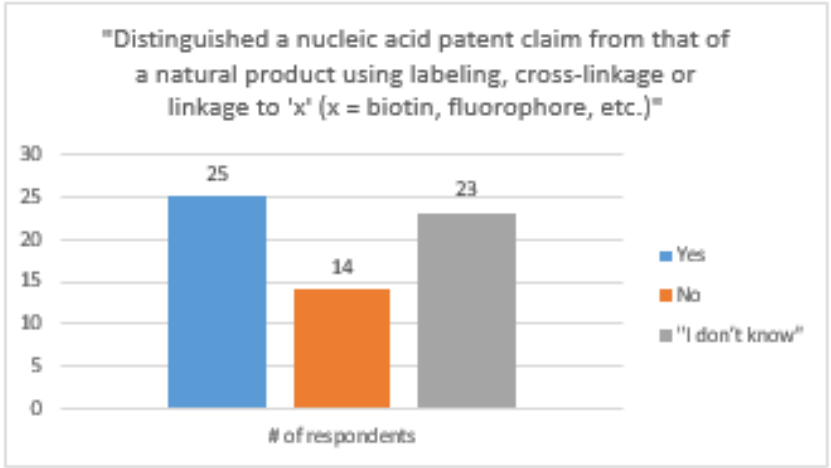




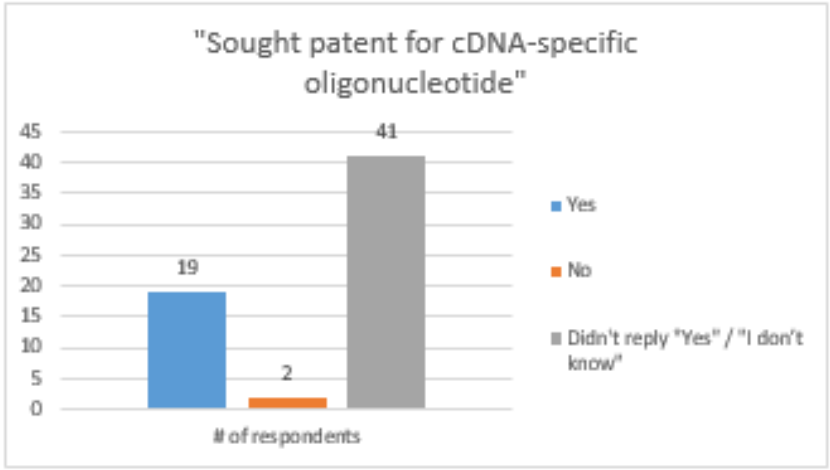
PATENTING STRATEGIES / RESPONSES, CONT. (2)

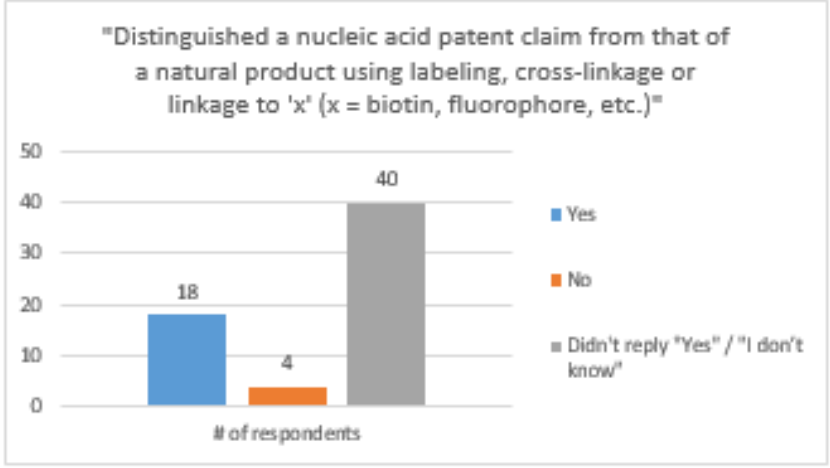
"To your knowledge, have any of these strategies been used at **your current university of employment** in a natural product patent application post-Myriad (since 2013)"





"In your own opinion, have those strategies **to which you responded "yes"** been generally successful in protecting existing patents of your university / obtaining new patents?"





R Software Code – Statistical Analysis of Qualtrics Data

```
###### R Analysis of Myriad Qualtrics Survey
###### Below: Sample code used for stats of each question
###### variable "x" below = question #

### Source Additional Functions
### Credit for function code to Professor Ole J. Forsberg
source("http://rfs.kvasaheim.com/rfs.R")

### Import Qualtrics Datafile
dt = read.csv('C:\\Users\\Smolive\\Desktop\\MQR.csv', header = TRUE)
attach(dt)

### Perform Shapiro-Wilk test for Normality
### null hypothesis : normally distributed population
### alpha level of 0.05
### if p-value > cannot reject null hypothesis
shapiroTest(x)

### Draw histogram with a Normal curve for reference
### Central Limit Theorem: is sample size "large enough"
### mound-shaped/bell curve, n=30 is enough
### U-shaped, preferred sample size of n=100
overlay(x)

### Determine sample size
length(x)

### Student's t-test
t.test(x)



###### Additional charts created from R
###### Question 7: Years in technology transfer

### Histogram
hist(Q7_1,
+ main="Histogram for Years in Tech Transfer",
+ xlab="Years",
+ border="black",
+ col="green",
+ las=1)

### Unlabeled boxplot
boxplot(Q7_1)
```

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