Presenting the Evidence for Patent Eligibility Reform: Part III - Case Studies and Litigation Data Highlight Additional Evidence of Harm (ipwatchdog.com)

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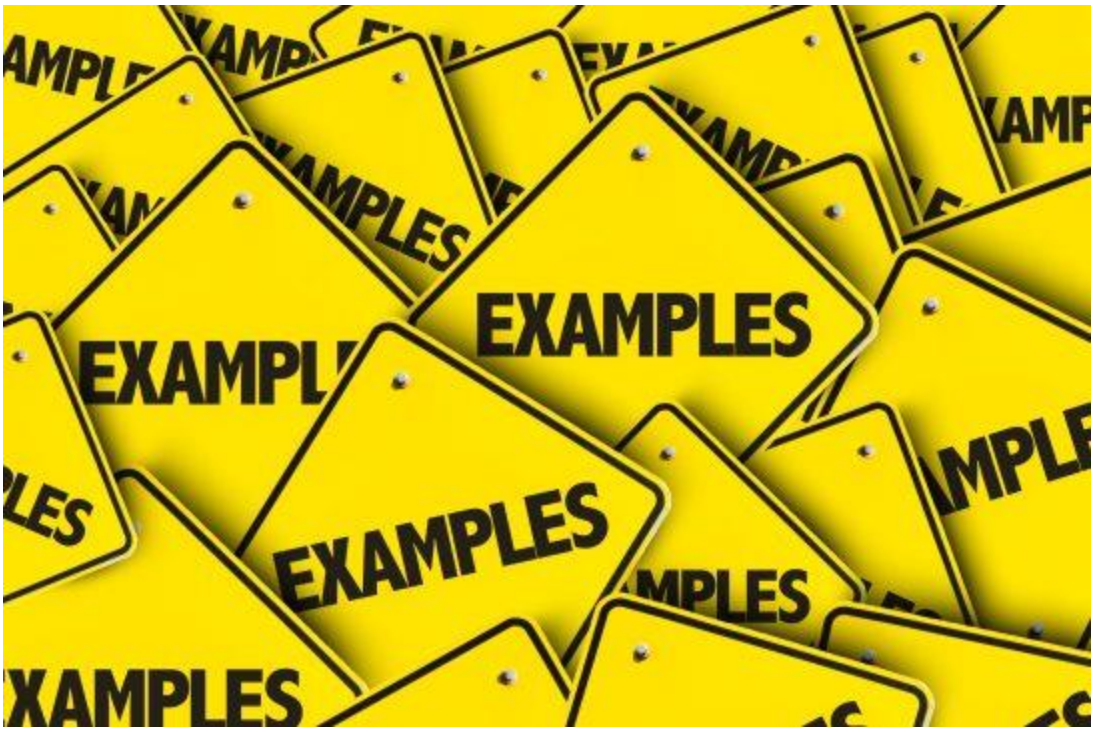
"The application [for a novel imaging diagnostic and predictive test for monitoring the progression of Alzheimer's disease] was abandoned [d]ue to the change in law brought on by *Mayo* and *Myriad*….and Alzheimer's patients are not receiving the benefit of the invention."




Systemic-level studies and data regarding impact on investment and innovation, as detailed in Part II of this series, are not the only way to demonstrate the substantial harm that the current state of patent eligibility has inflicted on the U.S. innovation ecosystem. Other robust evidence shows that current Section 101 law has harmed innovation by removing the incentives to develop and commercialize particular inventions of public importance. As another form of harm, the vagueness and breadth of the *Alice/Mayo* framework have also enabled accused infringers to transmogrify Section 101 into a litigation weapon in inappropriate cases that has created unnecessary burdens and costs on innovators and the courts.

## A. Numerous Diagnostics Were Not Commercialized Due to Section 101

The *Mayo and Myriad* decisions have had, and continue to have, a chilling effect on the investments needed to translate diagnostic-related inventions into clinical applications, particularly in fields such as autoimmune disease, Alzheimer's Disease, major depressive

disorders, brain cancer, and genetic disease. As the below examples show, commercial partners that had previously invested in developing these technologies commonly ceased doing so following *Mayo* and *Myriad*, either because existing patents were now vulnerable and new patents were no longer available, or because patent scope became so narrow as to be commercially worthless. Countless diagnostics, including those below, were not developed, and are not being developed.

## 1. Prominent University in the Midwest: Abandoned Lupus Diagnostic

Researchers at a prominent Midwest university developed a diagnostic test that helped physicians proactively treat Systemic Lupus Erythematosus (SLE). SLE is a disease where the body's immune system attacks its own tissues, causing inflammation, pain, and damage to vital organs. Severity can be mild to fatal, with renal damage being a major cause of mortality. SLE patients suffer from "flares," when symptoms suddenly appear, worsen quickly, and cause organ damage. It is very difficult to predict when symptom flares will occur and in which patients. Current patient monitoring measures levels of antibodies and immune factors that do not sufficiently correlate with flares, making it challenging to diagnose and manage a patient's treatment. As a result, an individual's treatment is largely trial and error.

Given the poor status quo for SLE patients, scientists at the Midwest university used genomic and proteomic technologies and identified clinically useful biomarkers for diagnosis, monitoring, and management of SLE. They determined, for the first time, that the following could be used successfully in diagnosing SLE patients: (a) panels of dysregulated serum proteins that predict disease activity or treatment outcome; and (b) interferon (IFN)-inducible serum

chemokines associated with SLE flare—including a panel of markers associated with renal disease, which as noted is a major cause of mortality in SLE patients.

Prior to the *Mayo* (2012) and *Myriad* (2013) decisions, the university filed for and obtained patent protection for the novel SLE diagnostic tests. The patents issued between 2006 and 2011, covering tests for gene expression of certain biomarkers to assess disease status. Post-*Mayo*/*Myriad* patent filings, however, met insurmountable obstacles during prosecution. While these later patent applications covered further aspects of the gene expression test and the chemokine biomarkers for predicting flares, the applications were abandoned because of new rejections under Section101 based on *Mayo* and *Myriad*.

Worse yet, the Midwest university's licensing of its SLE diagnostic technology was disrupted by the *Mayo* and *Myriad* decisions. The university had licensed the gene expression technology to a diagnostic company in 2007, and the chemokine biomarker technology was successfully licensed to a Fortune 500 company in 2010—all to develop and commercialize improved diagnostics to benefit SLE patients. But the licensees terminated the licenses based on the new vulnerability of the issued patents and the inability to obtain the full scope of patent protection with additional patents. Without patent protection, further capital investment into the platform was prohibitive. The university's promising diagnostic tests would have benefited SLE patients, but they have not been developed or commercialized given the lack of patent protection—amounting to a loss to the patients and a detriment to public health.

## 2. Prominent University on the East Coast: Abandoned Numerous Diagnostics

### *a. Abandoned Alzheimer's Diagnostic*

A researcher at a prominent East Coast university medical school redefined Alzheimer's disease biology that had significant implications for diagnostic testing. He developed a novel imaging diagnostic and predictive test for monitoring the progression of Alzheimer's disease. The test greatly reduced the time and cost of an imaging diagnostic that ultimately could be used for routine testing. The doctor received the AAIC Lifetime Achievement Award from the Alzheimer's Association for his work specializing in diagnostics for Alzheimer's disease.

The university filed for patent protection on the diagnostic imaging tests in 2003 and obtained two patents, in 2010 and 2012, prior to *Mayo* and *Myriad*. The patents were licensed to a commercial diagnostic imaging company for development. The university subsequently filed a continuation application to protect different aspects of the invention with similar diagnostic claims, but the application was rejected under Section 101 on account of *Mayo*. The application was abandoned, and no further patents were obtained to protect the full scope of the invention. Due to the change in law brought on by *Mayo* and *Myriad*, the university's licensed patents were deemed vulnerable, and the licensee ceased paying royalties, which would have funded further research needed to commercialize the technology. The diagnostic has not been successfully translated to the clinic, and Alzheimer's patients are not receiving the benefit of the invention.

### *b. Abandoned Major Depressive Disorder Diagnostic*

At the same university, a researcher presented the first evidence that late-life depression, a condition associated with increased risk for Alzheimer's disease, is accompanied by disturbances in central and

peripheral metabolism of amyloid-beta, a peptide implicated in Alzheimer's disease. The researcher developed a diagnostic test based on this discovery, and the university obtained a U.S. patent, issued in 2010, for a diagnostic test for major depressive disorders, before the *Mayo* and *Myriad* decisions. Between 2010 and 2014, the university filed four continuation applications with other diagnostic claims covering different aspects of the technology. Each application was rejected and later abandoned based on Section 101 grounds on account of *Mayo*. The university could not obtain any further patents covering the full scope of the invention. The sole patent that had issued in 2010 before *Mayo* and *Myriad* did not attract investment, and the technology was not translated to the clinic.

### *c. Abandoned Metastatic Cancer Diagnostic*

Researchers at an Interdisciplinary Melanoma Cooperative Group at the same prominent East Coast university developed a diagnostic test that could predict the risk of brain metastasis in melanoma patients when the patient was first diagnosed with the primary tumor. This research fulfilled a critical unmet need for melanoma patients. Brain metastasis in the metastatic melanoma patient population occurs rapidly, with a median survival of 4 months from diagnosis. Early prediction is thus critical to effective disease management and treatment. The university filed for patent protection in 2013. The application was abandoned in 2016 after receiving Section 101 rejections, relying on *Mayo* and *Myriad*. No further patents were pursued, and the university was unable to effect efforts to bring the diagnostic test to market.

### *d. Abandoned Schizophrenia Diagnostic*

This same university filed for and obtained patent protection in 2017 for detecting a genetic mutation that can be used to diagnose

schizophrenia. This new method was an advance in patient diagnosis and in public health generally. But the university's patent was limited in scope because, during prosecution, the university was compelled to add a "treatment" step to the diagnostic method claims to overcome Section 101 rejections under the *Mayo* framework. Importantly, this "combination" claim (including both diagnostic and treatment steps) decreased the value of the patent because the two steps are typically performed by multiple entities (e.g., a diagnostic company for the detection step and a medical facility for the treatment step), and enables users to avoid infringement even though they are in essence performing the invention and benefiting from the university's research and discovery.

Under the "divided infringement" doctrine, a "combination" claim can only be enforced when the two entities that perform the two different steps in the claim are working in concert, such as part of a joint enterprise. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015). This is a rare situation in the diagnostics field; the norm is a lab company performs the diagnostic testing and, independently, the physician treats the patient. As a result, such combination diagnosis-treatment claims have limited value, post-*Mayo/Myriad*, for attracting the commercial investment needed to translate the diagnostic to the clinic. Here, the patent in fact did not attract investment, and the institution abandoned efforts to translate the technology to the clinic.

***e. Abandoned Cancer Diagnostics***

The same university filed for and obtained patent protection in 2015 for detecting up?regulation of specific genes that predict prognosis of a cancer patient. That information can improve the physician's choice of the best treatment options for the cancer patient. The patent describes multiple ways to measure up-regulation of the specified

genes. The Patent Office limited the claims, however, to an immobilized platform technology, in order to overcome Section 101 rejections based on the Supreme Court's new patent-eligibility case law. The result: An infringing competitor could use a different platform technology to steal the heart of the invention yet circumvent the unduly narrow claims. In the end, the patent did not attract commercial investment, and the university abandoned efforts to translate the technology to the clinic.

### 3. Prominent Medical School on East Coast: *Abandoned Rare Disease Diagnostic*

The Director of the Center for Molecular Cardiology and Professor of Pediatrics and Genetics and Genomic Science at a prominent East Coast medical school developed an extensive program in genomics and gene investigation, focusing on traits associated with heart malformations. He is a distinguished recipient of many awards for his work on pediatric heart disease and was elected to the National Academy of Medicine.

One focus of his work was Noonan syndrome, a rare pediatric genetic disorder leading to abnormal physical development, including heart defects, unusual facial characteristics, short stature, and other physical problems and developmental delays. The Professor studied the genetic origins and pathogenesis of Noonan syndrome and developed a diagnostic test for early detection of the disease to enable early intervention. The medical school filed for patent protection on its Noonan syndrome diagnostic test in 2007 and obtained a patent in 2012, just after *Mayo* (March 20, 2012) and shortly before *Myriad* (June 13, 2013). The medical school then sought an additional patent to obtain full protection for its diagnostic compositions and methods. The Patent Office rejected the application under Section 101, citing *Mayo*. The university abandoned the

application and did not obtain any further patents to protect its invention.

Prior to *Mayo* and *Myriad*, the patented diagnostic test was licensed to a company that commercialized the genetic test.
After *Mayo* and *Myriad*, the licensee refused to pay royalties. Based on the issued patent's new vulnerability and the medical school's new inability to obtain any additional patents, no effort was taken to enforce the issued patents (which in turn impedes research institutions' ability to use patent royalties to fund the additional research and frustrates the purpose of the Bayh-Dole Act). Unable to recover proceeds on the first-generation tests, the medical school engaged in no further effort to commercialize second-generation improved diagnostic tests for Noonan Syndrome.

## B. Examples from Software and Other Tech Areas

As in the biotech and diagnostics field, the *Alice* and *Mayo* decisions had, and continue to have, a chilling effect in the computer and high-tech space. One difference is worth noting, however. With the rise of Big Tech and the concentration of market power in a few dominant firms, one of the most devastating effects of the legal uncertainty in patent-eligibility law is the devaluation of patent rights, which leads to rampant infringement (sometimes referred to as "efficient infringement") and scorched-earth litigation (often through concurrent attacks in the district courts and at the PTAB) in multiple attempts to invalidate patents—rather than licensing the patent rights of innovators and small- and medium-sized businesses.

### *1. Abandoned Improved Software for Monitoring Self-Service Terminals*

U.S. consumers enjoy the benefits of shopping using self-checkout terminals and banking using ATMs. These self-service terminals

(SSTs) allow customers to efficiently complete basic transactions without the need for a checkout clerk or bank teller. In 2019, the self-service technology market was estimated to be around $28.3 billion. By 2024, it is estimated that more than 4.3 million ATMs will be in use.

A U.S.-based corporation was seeking patent protection for its innovative software system to monitor operations of SSTs. Using the invention, operators could track which machines and/or parts of machines cause the most problems. The innovative software systems utilized operation data in conjunction with fault data, such as number of malfunctions and/or which part(s) malfunctioned, to identify parts that may routinely cause problems. The innovative software was able to distinguish a finicky part or machine with a high number of malfunctions per use from a machine that simply has a lot of malfunctions but has a low number of malfunctions per use. In other words, the software could identify if a part is truly the problem or if overuse is the problem and additional machines should be installed at a location.

During prosecution, an initial rejection under Section 101 was overcome, but the USPTO issued new Section 101 rejections following judicial decisions and new USPTO guidance. More rounds of prosecution resulted in costly attorney fees, and the company decided to simply abandon patent protection for the new software system. This result will likely lead to lower licensing revenue and thus fewer resources for the company to invest in R&D for other innovation.

### *2. Abandoned Improved Healthcare Account Processing Solutions*

In the United States, per capita healthcare spending was over $11,000 during 2019. Total health care costs were close to 18% of the entire

gross domestic product. One contributing factor to the rising cost of health care is the lack of cost transparency for the consumer.

Solarte Health, Inc. (Solarte), based in Minnesota and founded in 2013 by a family medical doctor, developed a platform to bring healthcare decisions into an open-market environment where patients can easily identify real costs of care defined by practitioners rather than by insurance companies. Solarte invented a healthcare account processing solution that (1) provided financial security when a participant experiences unexpected major medical expenses, (2) provided control of health care decisions to participants and providers, (3) reduced overhead and structural costs required to administer traditional health insurance plans, (4) reduced over-utilization and under-utilization of health care through a participant-controlled health care spending account, and (5) encouraged provider competition through the use of cash based, point-of-sale payments and transparent pricing.

Shortly after its founding, Solarte filed two utility patent applications in 2014 to protect its account processing inventions. Solarte was actively fundraising and also perfecting its prototype systems. Its founders believed that having U.S. patent protection would help secure investment from third parties, generate interest throughout the healthcare and insurance communities, and provide needed protections while it competed in the marketplace.

Unfortunately, the USPTO rejected Solarte's patent applications under Section 101 for allegedly being directed "towards the abstract idea of using rules to process a healthcare account transaction [using] conventional computer functions that do not add meaningful limits to practicing the abstract idea." The USPTO also contended that the inventions were directed to "predominantly a fundamental economic practice as it relates to the performance of a financial transaction in

the realm of commerce." Facing mounting legal costs to fight the USPTO rejections and uncertainty about whether further efforts would be fruitful, Solarte decided to abandon the two patent applications.

Again, the end-result is that Solarte will lose out on protecting its innovation, having fully described its details to the public through the application process. Without exclusivity, Solarte will be less able to capitalize on its innovation and less able to stop copycat infringers.

***3. Smartflash LLC v. Apple, Inc.***

In *Smartflash LLC v. Apple Inc.*, the Federal Circuit held three patents invalid as lacking an inventive concept—despite a prior jury finding that the claimed inventions provided a patentable improvement over the prior art. At the district court, the jury determined that each claimed invention provided a novel and non-obvious improvement over the prior art. After considering every prior art reference and combination put forth by the defendant, the District Court further found the jury's findings to be well-supported by the evidence. Nevertheless, the Federal Circuit determined that this was insufficient for eligibility, contending that "providing a distinct advantage over alternatives is not the test for eligibility."

This reasoning, however, is inconsistent with Supreme Court precedent. In *Alice*, the Supreme Court explained that exemplary claims are "patent-eligible because they improve[] an existing technological process." Yet, the Federal Circuit held the patents in *Smartflash* invalid for lacking an inventive concept, despite the jury's explicit finding and the district court's affirmation of that finding.

The *Smartflash* case demonstrates the problematic nature of the "inventive concept" which, under current Federal Circuit precedent,

allows for claimed inventions to be novel and non-obvious but not "inventive" enough to be eligible for patent protection. Section 101 was never intended to as a test for novelty and non-obviousness. Using it for that purpose is convenient for large companies wishing to take others' innovations for free, but demonstrably harmful to small innovative disruptors like Smartflash.

### *4. American Axle*

One of the most notable examples of confusion under Section 101 is *American Axle & Manufacturing, Inc. v. Neapco Holdings, LLC*. In this case, the Federal Circuit held as invalid a patent claiming a method of manufacturing a driveline propshaft containing a liner. The court believed the claim to be directed to a law of nature, and nothing more. The Court concluded that the claimed method does no more than claim a result—tuning a liner in a propshaft to reduce vibration—by applying "a natural law of relating frequency to mass and stiffness—i.e., Hooke's law."

Little needs to be added about the *American Axle* case. We have difficulty understanding how, in any reasonable patent system, anyone could conclude that a method for making a tangible item (such as an axle) is not even *eligible* for patent protection. Perhaps the claim is not novel or is obvious, but it certainly must be in that class of inventions that is "eligible" for patent protection, according to the words of the statute: "any new and useful process, machine, manufacture, or composition of matter." Indeed, our own government has said exactly that, stating in its May 2022 amicus brief in the case that "Under Section 101 as interpreted for more than 150 years, petitioner's claims recite a patent-eligible 'process.'" The outcome in *American Axle* epitomizes the confusion that pervades the analyses for other patents and patent applications.

### *5. Yu v. Apple*

*Yu v. Apple, Inc*. is another head-scratcher. The Federal Circuit invalidated a patent for an improved digital camera. The court saw the claim as being improperly directed to the patent-ineligible abstract idea of "taking two pictures (which may be at different exposures) and using one picture to enhance the other in some way." The court stated that this idea had been known by photographers for over a century and that only conventional camera components were recited to effectuate the resulting enhanced image.

This case is another example illustrating the confusion fomented by the current law. The invention was directed to a tangible item—a digital camera. It is in fact the prototypical invention. The law has indeed strayed a long way (in the wrong direction) from when Thomas Edison—perhaps the country's most well-known inventor—received patents on his Kinetograph in the 1890s.

In the final installment of this series, we will examine the cost and burden of this confusion around patent eligibility to U.S. courts and litigants.

*Note: The case studies included herein were provided to authors on condition of anonymity.*