Response to Request for Information

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Patent Eligibility Jurisprudence Study
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Introduction

In the past ten to fifteen years, the U.S. patent system has been under an extensive amount of stress from all branches of the federal government. For its part, the Supreme Court is now deciding patent cases at a rate not seen for almost a hundred years,[1] changing the law in all aspects of the patent system. Among these numerous changes were four decisions between 2010 and 2014 on patent eligibility doctrine under § 101.[2] These decisions severely restricted the inventions and discoveries that have long been considered patentable for over two centuries in the U.S. patent system.

These four decisions culminated in the "*Alice-Mayo* framework"—a two-factor inquiry that courts and the U.S. Patent & Trademark Office (USPTO) have applied since 2014 in assessing whether an invention or discovery is patentable subject matter under § 101.[3] The *Alice-Mayo* framework has created a tremendous amount of uncertainty for innovators and severely restricted the patent eligibility of high-tech and biopharmaceutical innovations. It has had a negative impact on both inventors and the companies working in the innovation industries that invest millions of dollars in

[1] *See* John F. Duffy, *The* Festo *Decision and the Return of the Supreme Court to the Bar of Patents*, 6 SUP. CT. REV. 273, 288 (2002).

[2] *See* Alice Corp. v. CLS Bank International, 573 U.S. 208 (2014); Association for Molecular Pathology v. Myriad Genetics, 133 U.S. 2107 (2013); Mayo Collaborative Services LLC v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012); Bilski v. Kappos, 561 U.S. 593 (2010).

[3] The two-factor inquiry is (1) determine whether the patent claim is directed to an abstract idea, natural phenomenon, or law of nature that are ineligible for patent protection, and, if it is, then (2) determine if the claim adds something more that transforms it into a patent-eligible application (an "inventive concept") of one of these ineligible categories or is this additional activity in the claim merely well-understood, routine, and conventional activity in the art. *See Alice*, 573 U.S. at 217-18; *Mayo*, 573 U.S. at 75-80.

creating the new products and services that drive economic growth, job creation and higher standards of living. Thus, it is undermining the longstanding comparative advantage by the U.S. in the world in securing reliable and effective patent rights for all innovators.

The *Alice-Mayo* framework is one of many recent changes to the U.S. patent system that has called into question the longstanding U.S. claim to a "gold standard" patent system as compared to the rest of the world.[4] As a result of the *Alice-Mayo* framework, the USPTO has denied patent applications or courts have invalidated issued patents in cutting-edge discoveries in medical care, such as treatments for breast cancer, diabetes, and strokes, among others.[5] Applying the *Alice-Mayo* framework, courts have invalidated patents covering classic nineteenth-century technologies, such as new methods for operating oil derricks and for constructing automobile axles.[6] Courts have invalidated twentieth-century innovations, such as holding that a claim "directed to" to a wireless electric garage door opener is an abstract idea.[7] This is an alarming shift from the historical approach of the U.S. in securing reliable and effective patent rights in new innovations, which has been a key driver of economic growth in the U.S.[8]

It is even more concerning in a global economy in which R&D investments and the venture capital financing that are the lifeblood of innovation can easily move from one country to another in search of more reliable legal security in the fruits of inventive labors. Historically, it was the U.S. that became the home to innovators and R&D financing. Even with period upheavals in U.S. patent policy over the past two centuries, the U.S. often forged ahead when other countries hesitated in securing patents in cutting-edge discoveries and inventions, such as in biotechnology and computer

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[4] *See* Kevin Madigan & Adam Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, IPWATCHDOG (Dec. 15, 2019), https://www.ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id=116984/; Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017).

[5] *See id.* at 955-959 (identifying patent applications for significant biomedical tests rejected by USPTO). For a few examples of the many patents invalidated by courts, *see* Cleveland Clinic Found. v. True Health Diagnostics LLC, 760 Fed. Appx. 1013 (Fed. Cir. 2019) (nonprecedential) (invalidating a patent on a biotech-based medical test for detecting heart disease as covering a patent-ineligible law of nature); Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019) (invalidating a patent on a biotech-based medical test for identifying neurological disorders as covering a patent-ineligible law of nature); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015) (invalidating a patent on non-invasive prenatal test using fetal DNA found the blood of the mother as covering a patent-ineligible law of nature and natural phenomenon);

[6] *See* American Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1288 (Fed. Cir. 2020) (invalidating a patent on a method of manufacturing an automobile axle as claiming a law of nature); TDE Petroleum Data Solutions v. AKM Enterprise Inc., 657 Fed. Appx. 991 (Fed. Cir. 2016) (invalidating a patent on a method of operation of an oil derrick as claiming an abstract idea)

[7] *See* Chamberlain Group, Inc. v. Techtronic Industries Co., 935 F.3d 1341, 1348-49 (Fed. Cir. 2019).

[8] *See* Stephen Haber, *Patents and the Wealth of Nations*, 23 GEO. MASON L. REV. 811 (2016) (surveying historical evidence and economic studies confirming that patents are a key factor in successful innovation economies); B. ZORINA KHAN, THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790-1920 (2005) (detailing the key role that reliable and effective property rights in patents have served in spurring markets and economic growth in the U.S.). An economic study using data from the USPTO found that patents significantly increase a startup's chances of obtaining venture capital financing, and thus significantly increases a startup's chances in growing into a small business in the marketplace. *See* Joan Farre-Mensa et al., *What is a Patent Worth? Evidence from the U.S. Patent "Lottery,"* 75 J. FINANCE 639 (2020), https://ssrn.com/abstract=2704028. Notably, small businesses create 65.9% of net new jobs in the country. *See* SMALL BUSINESS ADMINISTRATION, OFFICE OF ADVOCACY, FREQUENTLY ASKED QUESTIONS (June 2018), https://www.sba.gov/sites/default/files/advocacy/Frequently-Asked-Questions-Small-Business-2018.pdf.

software.[9] China and European countries are now the ones forging ahead and securing reliable and effective patents in innovation that the U.S. no longer protects due to the closing of its patent system under the *Alice-Mayo* framework.[10]

In response to the request for information on patent eligibility jurisprudence and its impact on the innovation industries, this comment will first detail the indeterminacy of the *Alice-Mayo* framework in which courts invalidate patents on innovations that have long qualified for patent protection in the U.S. Second, it details data from U.S. patent applications between 2014 and 2017, identifying 1,310 U.S. patent applications that were abandoned after receiving an initial rejection under the *Alice-Mayo* framework, but patents issued on these inventions or discoveries in China, Europe, or both. It further assesses this data on a more granular level, identifying a significantly negative impact on the biopharmaceutical sector. Third, it identifies the positive effect of the 2019 patent eligibility guidelines adopted by the USPTO, but then explains why the 2019 guidelines cannot resolve the systemic uncertainty created by the *Alice-Mayo* framework, as applied by courts and by future Directors of the USPTO. Lastly, it reviews briefly some of the economic and historical evidence showing a strong correlation between reliable and effective patent rights and economic growth, and further reviews some of the data showing that the loss of reliable and effective patent rights due in part to the *Alice-Mayo* framework is undermining innovation and economic growth.

The Patent Eligibility Quagmire in the Courts

The Supreme Court returned to patent eligibility doctrine in 2009, and the Court set forth the new *Alice-Mayo* framework in its entirety by 2014, but seven years later, patent eligibility jurisprudence continues to remain fundamentally unsettled. The doctrine is marked by unpredictability and indeterminacy. Courts are dissecting patent claims into their respective elements, identifying these elements as abstract ideas, laws of nature, or natural phenomena, and concluding that the claims are "directed to" ineligible subject matter that lack an inventive concept that saves the patent from judicial invalidation. This jurisprudence is significant for several reasons.

First, patent eligibility jurisprudence is no longer "only a threshold test," as the Court rightly framed the nature of the § 101 inquiry in its 2009 decision in *Bilski v. Kappos*.[11] Since 2014, patent eligibility doctrine stopped serving as only a "coarse filter" that is applied before a court applies

[9] *See* Madigan & Mossoff, *supra* note 4, at 942-946 (detailing this historical approach in biotech and software).

[10] *See id. See also* Elizabeth Chien-Hale, *A New Era for Software Patents in China*, LAW360 (May 25, 2017), https://www.law360.com/articles/924934/a-new-era-for-software-patents-in-china ("China's opening up [of its patent system to new high-tech innovation] contrasts with the United States' move to cut back on business method patents and software patents."); Preetika Rana, *Your Cancer Drugs May Soon Be Discovered in China*, WALL STREET JOURNAL (Apr. 11, 2017), https://www.wsj.com/articles/china-emerges-as-powerhouse-for-biotech-drugs-1491816607 (reporting on R&D investment shifting to China given the inability of U.S. companies to obtain patents for their biotech drugs); Jack Ellis, *China Relaxes Rules on Software Patentability – and the United States Loses More Ground*, IAM (Mar. 3, 2017), https://www.iam-media.com/law-policy/china-relaxes-rules-software-patentability-and-united-states-loses-more-ground. ("China's apparent embrace of software patents stands in stark contrast to the situation in the United States, which many would see as the traditional home of the software industry.").

[11] *Bilski*, 561 U.S. at 602.

the more fine-grained doctrinal requirements of novelty, nonobviousness, and disclosure.[12] Instead, the *Alice-Mayo* inquiry is now an all-pervasive and principal feature of patent law generally. An empirical study by Robert Sachs in 2019 found that court decisions applying § 101 after 2014 jumped 730% with a 659% increase in the number of litigated patents.[13] Sachs found that, as "[c]ompared with the five years prior to *Alice* [reaching back to *Bilski* in 2009], there has been a 1056% increase in the number of decisions finding ineligible claims, and a 914% increase in the number of invalidated patents" between 2014 (when *Alice* was decided) and 2019.[14]

Second, the courts are applying the *Alice-Mayo* framework in a willy-nilly fashion in which they ignore the longstanding rule in patent law that claimed inventions should be construed and assessed as a whole, and instead courts are dissecting claims into elements to find them to be "directed to" ineligible abstract ideas or laws of nature. There are innumerable examples and thus a few illustrative cases will suffice for the purpose of brevity. In *TDE Petroleum Data Solutions v. AKM Enterprises*, the Federal Circuit affirmed the district court's decision that a patent on a process for operating an oil drilling rig was invalid for claiming an "abstract idea."[15] In this case, the Federal Circuit dissected the patent claim into separate elements and ignored other express elements that comprised the claimed invention as a whole. In its opinion, the Federal Circuit focused solely on a single element in the claim, and then asserted that the invention as a whole performed only the "generic computer functions" of this single element.[16] The Federal Circuit disintegrated the claimed invention into a single element—reframing the invention as a whole as simply generic and abstract data analysis. The court ignored other claim elements, such as the express terms "well operation" and other language in the patent that made it clear the claimed invention as a whole was for an industrial process in running an oil-drilling operation on an oil rig.[17]

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[12] *See* Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos, 75 Fed. Reg. 43,922, 43,923-24 (July 27, 2010), http://www.uspto.gov/patents/law/exam/bilski_guidance_27jul2010.pdf ("Section 101 is merely a coarse filter and thus a determination of eligibility under § 101 is only a threshold question for patentability. Sections 102, 103, and 112 are typically the primary tools for evaluating patentability unless the claim is truly abstract . . . ."); Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 869 (Fed. Cir. 2010) ("[A] patent that presents a process sufficient to pass the *coarse eligibility filter* may nonetheless be invalid as indefinite because the invention would not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim.") (emphasis added).

[13] *See* Robert Sachs, Alice*: Benevolent Despot or Tyrant? Analyzing Five Years of Case Law Since* Alice v. CLS Bank*: Part I*, IPWATCHDOG (Aug. 29, 2019), https://www.ipwatchdog.com/2019/08/29/alice-benevolent-despot-or-tyrant-analyzing-five-years-of-case-law-since-alice-v-cls-bank-part-i/id=112722/.

[14] *Id.*

[15] *See TDE Petroleum Data Solutions*, 657 Fed. Appx. at 993.

[16] *Id.*

[17] Claim 30 in the invalidated patent in *TDE Petroleum* paralleled precisely the same substance, structure, and language of the claim that the Supreme Court affirmed as valid in *Diamond v. Diehr*, 450 U.S. 175 (1981). The Diehr patent and TDE Petroleum's patent are essentially the same: both patents claim a software-based method for operating an industrial process. The Diehr patent claimed a new process for curing rubber in a machine using a computer program. *Id.* at 177. TDE Petroleum's patent claims a new process for operating an oil drill on an oil rig using a computer program. The two patent claims are also similar in both their form and substantive elements. The patent claim at issue in Diehr had four steps: (1) a definition of initial data, (2) collection of new data from the machine implementing the industrial process, (3) analysis of the data, and (4) control of the industrial process. *Id.* at 179 n.5. In *TDE Petroleum*, Claim 30 had essentially the same steps as the Diehr patent; after a preamble explicitly stating that the claim is directed to running a "well operation," it detailed steps in a process for operating an oil-drilling operation on an oil rig using a computer program. As the *Diehr* Court, industrial processes like drilling oil or curing rubber are clearly patent eligible under § 101. *Id.* at 184 ("The respondents' claims describe in detail a step-

Repeating this same methodological error in *American Axle v. NEAPCO*, the Federal Circuit ignored the express claim elements setting forth physical requirements in the use of a method of manufacturing a driveshaft. In this case, the claim instructed a manufacturer to tune the mass and stiffness of a liner, insert the liner into a hollow driveshaft, and require that the liner absorb two modes of vibrations (shell and bending) via two mechanisms (resistive and reactive absorption).[18] Despite the district court asserting it was focusing on the "claims as a whole,"[19] the district court in fact dissected the claim into its elements and focused solely on the "tuning" elements as the entire gist of the claimed invention. It thus concluded that the claim was merely an application of the laws of thermodynamics (Hooke's law and friction damping).[20] The Federal Circuit agreed—in two separate opinions.[21] In sum, a district court and the Federal Circuit disintegrated a claim into its distinct elements, ignored specific physical limitations set forth in some claim elements, and concluded that the claimed manufacturing method was merely "directed to the utilization of a natural law (here, Hooke's law and possibly other natural laws)."[22]

As Judge Kimberly Moore aptly observed in her (first) dissenting opinion in *American Axle*, the panel's reasoning is "goulash [that] is troubling and inconsistent with the patent statute and precedent."[23] All inventions are by necessity applications of abstract ideas and laws of nature, and thus the method of courts in construing patent claims in cases like *TDE Petroleum* and *American Axle* would call into question the validity of patents long issued to American innovators. This includes the first U.S. patent issued to Samuel Hopkins in 1790 for his discovery of a new method of making potash[24] and Samuel Morse's first claim on his electromagnetic telegraph (affirmed as valid by the Supreme Court in 1854).[25] In *American Axle*, Judge Moore concluded her (first) dissent with the admonition that the "majority worries about result-oriented claiming; I am worried about result-oriented judicial action." In her (second) dissent, she rightly identified the majority's analysis as "chimeric" that is "bound to cause confusion."[26]

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by-step method for accomplishing [a rubber-curing process]. Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws.").

[18] American Axle & Mfg., Inc. v. Neapco Holdings LLC, 939 F.3d 1355, 1359-60 (Fed. Cir. 2019), *reh'g granted, opinion withdrawn*, 966 F.3d 1294 (Fed. Cir. 2020), and *opinion modified and superseded on reh'g*, 967 F.3d 1285 (Fed. Cir. 2020).

[19] *Id.* (quoting American Axle & Mfg, Inc. v. Neapco Holdings, LLC, 309 F. Supp. 3d 218, 221 (D. Del. 2018)).

[20] *Id.* Hooke's law is the linear relationship between force F and displacement x of a spring with stiffness k, specifically F=kx. *See America Axle*, 309 F. Supp. 3d at 225.

[21] *See supra* note 18.

[22] *American Axle*, 939 F.3d at 1366.

[23] *American Axle*, 939 F.3d at 1375 (Moore, J., dissenting).

[24] *See* U.S. Patent No. X00001 (granted July 31, 1790). Hopkins' novel method comprised well-known steps at the time, such as burning and dissolving ash. His sole discovery was improving the timing and specific order of the steps. *See* Henry M. Payntor, The First Patent (rev., 1998), http://www.me.utexas.edu/~longoria/paynter/hmp/The_First_Patent.html.

[25] *See* 56 U.S. (15 How.) 62, 112 (1854) ("We perceive no well-founded objection . . . to his right to a patent for the first seven inventions set forth in the specification of his claims."); *see also* Adam Mossoff, O'Reilly v. Morse *and Claiming a "Principle" in Antebellum Era Patent Law*, 71 CASE W. RES. L. REV. 735, 750-51 (2020) (quoting and discussing claim one).

[26] *American Axle*, 939 F.3d at 1375 (Moore, J., dissenting).

Data on the Examination of Patent Eligibility at the USPTO

In its first years applying the *Alice-Mayo* framework, the USPTO initially fared no better than the courts. A dataset of patent applications abandoned between 2014 and 2017 created by Robert Sachs and David Kappos found "1,310 applications were abandoned following rejections under the *Alice-Mayo* framework for lack of patent eligible subject matter, and yet had issued patent family members in either China or Europe."[27] (An earlier report of the dataset mistakenly included false positives that reported 1,694 abandoned applications, and this was corrected in a follow-on published report with the total number of patent applications at 1,310.[28])

The Sachs-Kappos dataset, updated and revised as of September 2019,[29] revealed that a significant number of the technologies that are being abandoned in the United States—and at the same time being issued as patents by the European Patent Office (EPO), China, or both—cover innovations in medical treatments and the life sciences.[30] This conclusion was reached via searching abstracts of the rejected and abandoned applications for instances of over 300 keywords and terms. The keywords were drawn from the Center for Disease Control's 2017 report on endemic diseases and leading causes of death, including terms like heart failure, cancer, Alzheimer's, diabetes, stroke, coronary, and others. The results showed that 618 of the 1,310 applications were directed to various aspects of diagnosis or treatment of the diseases related to these keywords—thus 47% of abandoned applications include many potential breakthroughs in the identification and treatment of the most prevalent and devastating illnesses facing people today.

A more granular analysis of the 618 healthcare-related technologies showed cancer treatments to be the most prominent category of abandoned or rejected applications, making up 150 (or about 24%) of the total. These innovations targeted a wide range of cancers, including carcinoma, leukemia, lymphoma, mesothelioma, and melanoma. Research and innovation aimed at combating and ultimately putting an end to these deadly cancers continues to be the focus of initiatives such as the National Cancer Institute's Cancer Breakthroughs 2020 (formerly Cancer Moonshot 2020), and yet the US patent system is rejecting applications directed to technologies that just might be at the forefront of the next great medical breakthrough.

After cancer-related patent applications came healthcare and information technology patent applications (103, 17%) and personalized medicine at 64 (10%). These two categories covered a variety of diagnostic and treatment methods aimed at a range of illnesses, including new innovations in diagnostic imaging and gene sequencing. Rounding out the results were a number of categories including, cardiovascular disease, infectious disease, gastrointestinal disorders, gene therapies, endocrine disorders, autoimmune diseases, and neurological disorders.

Another important finding in the Sachs-Kappos dataset is a blatant overlap in legal grounds of rejection in the 1,310 applications that confirms the oft-repeated point that the *Alice-Mayo*

[27] Madigan & Mossoff, *Five Years Later*, *supra* note 4.

[28] *See supra* note 4.

[29] The updated dataset is available here: http://sls.gmu.edu/cdn/files/Sachs_Kappos_1310-ForPublication1.xlsm. Questions about this dataset should be directed to Robert Sachs at rsachs@patentevaluations.com.

[30] The following paragraphs are reproduced from Madigan & Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, *supra* note 4.

framework conflates different legal and policy requirements. Coding for different types of rejections in §§ 101, 102, 103 and 112 confirmed that the "inventive step" inquiry in step two of the *Alice-Mayo* framework blends the nonobviousness inquiry under § 103 with the patent eligibility inquiry under § 101. The largest single overlap in patentability requirements for rejection was between §§ 101 and 103, with 379 (29%) of the total 1,310 applications. If the rejection(s) combined §§ 101, 103 and 112, the percentage jumped to over 50%, confirming that nonobviousness and overbreadth are being conflated with patent eligibility in significant numbers.

These data suggest that healthcare-related technologies have borne the brunt of the invalidation contagion wrought by the *Alice-Mayo* framework, and that innovations to diagnose or cure diseases are being abandoned in the United States. Significantly, these same innovations are receiving patent protection in China and Europe. Additionally, the overlap of §§ 101 and 103 rejections of these patent applications confirms the oft-heard criticism that the *Alice-Mayo* framework conflates different legal and policy concerns in distinct patentability requirements.

Why the 2019 Patent Eligibility Guidelines Cannot Cure the Problem

In January 2019, USPTO adopted new examination guidelines under the *Alice-Mayo* framework. Andrei Iancu, the USPTO Director in 2019, stated that the new guidelines would "improve certainty and reliability" in how examiners would use § 101 in reviewing patent applications.[31] A recent empirical study released by the USPTO has confirmed that the 2019 guidelines have brought greater certainty to the examination of patent applications.[32]

However, the USPTO is limited in how much it can achieve with the 2019 guidelines, and ultimately the 2019 guidelines cannot solve the patent eligibility quagmire. First, the USPTO has no authority over how the courts will apply the *Alice-Mayo* framework to the patents the USPTO now finds to be valid under § 101. This was confirmed shortly after the 2019 guidelines went into effect when the Federal Circuit applied the *Alice-Mayo* framework in *Cleveland Clinic v. True Health Diagnostics* to invalidate another patent under § 101 on a breakthrough diagnostic method for detecting heart disease; the court held that the patent claimed a "law of nature."[33] In *Cleveland Clinic*, the patent owner argued that the Federal Circuit should defer to the USPTO's examination guidelines in finding this invention to be patent eligible. The Federal Circuit rejected this contention, stating bluntly that "we are not bound by [the USPTO's] guidance."[34]

[31] U.S. Patent and Trademark Office announces revised guidance for determining subject matter eligibility (Jan. 4, 2019), https://www.uspto.gov/about-us/news-updates/us-patent-and-trademark-office-announces-revised-guidance-determining-subject.

[32] Andrew A. Toole & Nicholas A. Pairolero, *Adjusting to* Alice: *USPTO Patent Examination Outcomes after* Alice Corp. v. CLS Bank International, IP DATA HIGHLIGHTS, No. 3 (USPTO Office of the Chief Economist, Apr. 2020), https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf.

[33] *See* Cleveland Clinic Found. v. True Health Diagnostics LLC, 760 Fed. Appx. 1013 (Fed. Cir. 2019) (nonprecedential).

[34] *See id.* at 1020 ("While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law.").

Second, and just as important, the reforms represented by the 2019 guidelines can be easily undone by the same administrative fiat by which they were adopted. Thus, the 2019 guidelines cannot offer the necessary promise of long-term permanence and stability for the companies in the biopharmaceutical sector with multi-year time horizons and billions in research and development at stake. Inventors and companies making long-term R&D investment decisions need to rely on a stable set of legal rules in order to research, develop, and commercialize innovative medical treatments and other new technologies. Regulatory changes in examination guidelines that can be potentially changed with each change in the administration in the Executive Branch cannot provide this requisite stability and reliability. For these reasons, while providing greater certainty and stability for patent applicants, the 2019 guidelines can neither prevent the continued willy-nilly application of the *Alice-Mayo* framework by courts in invalidating issued patents nor provide the requisite long-term legal certainty and reliability to innovators.

Preliminary Data on the Impact of Uncertainty and Unreliability under § 101

Given widespread misunderstandings and misinformation in patent policy discussions about the relationship between patents, economic growth, and innovation, it is necessary to first set the context of the empirical standards that are properly used in evaluating a legal doctrine like patent eligibility and the impact this doctrine has on the innovation economy. A recent review of the economic and historical studies of the relationship between patents, innovation, and economic growth found the substantial weight of evidence supporting a finding of a "causal relationship between strong patents and innovation."[35] In this review, Professor Stephen Haber found that "there are no wealthy countries with weak patent rights, and there are no poor countries with strong patent rights."[36] This establishes the same presumptive burden on behalf of patents that is established by the same overwhelmingly positive correlations between economic growth and other property rights, such as real estate; accordingly, those who claim otherwise bear the burden of proving a negative relationship.[37]

A recent survey by Professor David Taylor of investors and representatives from companies in the innovation industries reported as its "first principal finding [that] investors who responded to the survey overwhelmingly believe patent eligibility is an important consideration when their firms decide whether to invest in companies developing technology."[38] This is consistent with the findings and studies reviewed by Professor Haber. More specifically, Professor Taylor found that "overall 62% of the investors agreed that their firms were less likely to invest in a company developing technology if patent eligibility makes patents unavailable, while only 20%."[39] Similar

[35] Haber, *supra* note 8, at 834.

[36] *Id.* at 815.

[37] *See id.* at 834 ("Evidence and reason therefore suggest that the burden of proof falls on those who claim that patents frustrate innovation."). *Cf.* Letter from law professors, economists and former government officials to Makan Delrahim, Assistant Attorney General, Antitrust Division, U.S. Dep't of Justice (Feb. 13, 2018), https://cpip.gmu.edu/wp-content/uploads/sites/31/2018/02/Letter-to-DOJ-Supporting-Evidence-Based-Approach-to-Antitrust-Enforcement-of-IP.pdf ("It bears emphasizing that no empirical study has demonstrated that a patent-owner's request for injunctive relief after a finding of a defendant's infringement of its property rights has ever resulted either in consumer harm or in slowing down the pace of technological innovation.").

[38] David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019, 2027 (2020).

[39] *Id.* at 2027-28.

to other empirical studies,[40] Professor Taylor found that the significance of the availability of and reliance on patents varied between different sectors of the U.S. innovation economy, such as between biotechnology and software/Internet services.[41] In fact, consistent with the data on abandoned patent applications in the Sachs-Kappos dataset that the hardest hit sectors of the innovation economy have been in biotech and healthcare services,[42] Professor Taylor similarly found the most significant "negative impact of the Supreme Court's eligibility cases generally on investment . . . in terms of its impact on public health: the biotechnology, medical device, and pharmaceutical industries."[43] Still, Professor Taylor's survey finds that "the results show the Court's decisions [on patent eligibility doctrine] have negatively impacted each and every area of technological development studied" in his survey, including even in software.[44] This identified negative relationship between the *Alice-Mayo* framework and investment decisions driving the U.S. innovation economy is consistent with the many studies consistently finding a positive relationship between reliable and effective patent rights and economic growth.[45]

Other studies have provided additional data that the U.S. patent system is in distress, and that the U.S. innovation economy is faltering in important respects. The World Intellectual Property Organization reported a 1.6% drop in U.S. patent filings in 2018—the first decline since 2009 when the U.S. was in the midst of the Great Recession.[46] In fact, the decline in U.S. patent applications in 2018 is not associated with either an economic recession or war, the two factors that have historically correlated with declines in patent applications in the U.S. The 2018 decline in U.S. patent applications is consistent with the findings by Professor Taylor of reduced investments in patent-based innovations.

Perhaps more significantly, is that the U.S. experienced a drop in patent applications as compared to China and Europe. The decline in the U.S. contrasts with patent filing activities in China and in Europe, which each saw a 11.6% and 4.7% *growth* in their patent applications in the same year.[47] The EPO also granted 20% more patent applications in 2018 than it did in 2017.[48] These numbers are consistent with the conclusion that the reduction in U.S. patent application filings is not a worldwide phenomenon, indicating that it is driven by U.S.-specific factors like the availability of and certainty in patent protections for innovations in the U.S. Lastly, the relative decline in the U.S. is consistent with the Sachs-Kappos dataset on patent applications of the 1,310 abandoned U.S. patent applications for inventions that received patents in China, in Europe, or both.

Relatedly, the Bloomberg Innovation Index, which tracks things like research and development spending, reported that the U.S. fell out of the top ten global innovation economies for the first

[40] *See* Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255 (2009).

[41] Taylor, *supra* note 38, at 2027-28.

[42] *See supra* notes 29-30, and accompanying text.

[43] Taylor, *supra* note 38, at 2030.

[44] *Id.* at 2028.

[45] *See supra* notes 35 -37, and accompanying text.

[46] WIPO, WORLD INTELLECTUAL PROPERTY INDICATORS 7 (2019), https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2019.pdf.

[47] *Id.*

[48] *Id.* at 18.

time in 2021.[49] In 2021, eight of the top ten are European countries with South Korea ranked first and Israel ranked seventh. Again, this and other related data are consistent with the studies that have found that reliable and effective patents correlate with innovation and economic growth, and with the Sachs-Kappos datasets and studies like those of Professor Taylor's that confirm the converse truth that weakened and unpredictable patent protections have a negative impact on investors and companies working in the U.S. innovation economy.

Conclusion

The U.S. patent system was long recognized as the "gold standard" among world patent systems.[50] Patented innovations drove the Industrial Revolution in the nineteenth century, the computer and biotech revolutions of the twentieth century, and the mobile revolution of the early twenty-first century. David Kappos, former Director of the USPTO, once observed that the U.S. patent system was "the greatest innovation engine the world has ever known."[51] Unfortunately, the ability of the U.S. patent system to continue to foster the next generation of innovations is in doubt.

There are many causes for concern in the U.S. patent system, but a principal cause is the *Alice-Mayo* framework for determining patent eligibility under § 101. As a result of the *Alice-Mayo* framework, the U.S. patent system is increasingly mired in legal uncertainty and lack of reliability in patents that are issued by the USPTO. Early data suggest this is having a negative impact on patent-intensive sectors of the U.S. innovation economy, just as reliable and effective patent rights have long been shown to have a positive impact on the thriving innovation economies.

There should be further research and analysis of the *Alice-Mayo* framework, but the continuing legal quagmire and preliminary data are significant enough to justify the conclusion that the *Alice-Mayo* framework is causing harm to innovators and the U.S. innovation economy. In order to ensure that policy debates are not hijacked by rhetoric based on unsubstantiated claims and secret data,[52] scholars should ensure that their data is accessible, their analysis is understandable, and the means by which they draw their conclusions in both content and method is independently verifiable. It is imperative, in the words of former USPTO Chief Economist, Alan Marco, that there be evidence-based policymaking, and not policy-based evidence-making,[53] especially when it comes to fixing the engine of innovation that is the U.S. patent system.

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[49] *See* Michelle Jamrisko, Wei Lu & Alexandre Tanzi, *South Korea Leads World in Innovation as US Exits Top Ten*, BLOOMBERG (Feb. 3, 2021), https://www.bloomberg.com/news/articles/2021-02-03/south-korea-leads-world-in-innovation-u-s-drops-out-of-top-10.

[50] *See* Madigan & Mossoff, *Turning Gold to Lead*, *supra* note 4, at 940. *See also* Adam Mossoff, *Institutional Design in Patent Law: Private Property Rights or Regulatory Entitlements*, 92 SO. CAL. L. REV. 921, 936 (2019) ("Key elements of modern patent systems around the world today were copied from the U.S. patent system . . . .").

[51] Innovation Act of 2013: Hearing on H.R. 3309 Before the Comm. on the Judiciary, 113th Cong. (Oct. 29, 2013) (statement of David J. Kappos, Partner, Cravath, Swaine & Moore LLP), at 2.

[52] *See, e.g.*, David L. Schwartz & Jay P. Kesan, *Analyzing the Role of Non-Practicing Entities in the Patent System*, 99 CORNELL L. REV. 425 (2014) (analyzing and critiquing the study by James Bessen and Michael Meurer that is the basis of the oft-repeated claim that "patent trolls" imposed $29 billion in costs on the economy in 2011); Adam Mossoff, *Repetition of Junk Science and Epithets Does Not Make Them True*, IPWATCHDOG (Nov. 19, 2015), https://www.ipwatchdog.com/2015/11/19/repetition-of-make-them-true/id=63302/.

[53] Alan Marco, *Why the patent system should look more like Indiana and less like Kentucky*, TEDxTysons (Aug. 3, 2017), https://youtu.be/HJhSD8ABt3s?t=759.