Before the
U.S. Patent and Trademark Office

In the Matter of

Request for Comments on
The Current State of Patent Eligibility Jurisprudence in the United States, and How the Current Jurisprudence Has Impacted Investment and Innovation, Particularly in Critical Technologies like Quantum Computing, Artificial Intelligence, Precision Medicine, Diagnostic Methods, and Pharmaceutical Treatments.

Docket Number PTO-P-2021-0032

Comment of A. Sasha Hoyt

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October 12, 2021

Dear Commissioner Hirshfeld:

In response to Section I.3.d of the Topics for Public Comment as provided in the Request for Comment published in 86 Fed. Reg. 36257, please accept this letter and the enclosed draft of my student Note, "The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies." My Note will be published in Volume 79 of the *Washington and Lee Law Review*. The heart of my Note is an empirical study of venture capital (VC) investment in disease diagnostic technologies before and after *Bilski* and *Mayo*. My study and its results are summarized below.

As background, I am currently a third-year law student at the at Washington and Lee University School of Law. I submit this Comment in my individual capacity, and I do not have any financial or other personal interest regarding the subject of this study. Rather, my interest is in seeing that the patent laws operate in a way that optimally promotes innovation.

A. Issue

Medical diagnostic tests are routinely used in the practice of medicine to permit physicians to identify diseases and conditions in a patient. Diagnostics can also be used preventatively to screen apparently healthy patients for a condition or disease, and to assist with detection in its earlier stages and improve patient outcomes. And although the benefits of diagnostic tests to society are often self-evident, economic concerns may weigh against development of tests for more uncommon conditions and diseases absent the incentives created by the availability of patent rights.[1] These concerns stem in part from uncertainty regarding patent eligibility of medical diagnostic methods following the Supreme Court's decisions in *Bilski v Kappos*[2] and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[3] and the Federal Circuit's application of the *Alice/Mayo* test

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1 *See* Christopher M. Holman, *The Critical Role of Patents in the Development, Commercialization, and Utilization of Innovative Genetic Diagnostic Tests and Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 297, 301 (2015) (noting "[t]he fundamental challenge in developing molecular diagnostic tests is identifying and validating clinically significant biomarkers" and explaining that "substantial investment is necessary to support the lengthy and labor-intensive research efforts required to discern and validate . . . biomarkers").

2 561 U.S. 592 (2010).

3 566 U.S. 66 (2012).

in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,[4] and *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC.*[5] Concerningly, "[s]ince *Mayo*, [the Federal Circuit has] held every single diagnostic claim in every case before [it] ineligible."[6]

With this track record of diagnostic methods being patent-ineligible under § 101, major investors likely have a reduced incentive to invest tens, if not hundreds, of millions of dollars[7] in the research and development of a diagnostic.[8] VC firms in particular play a critical role in the financing of start-up companies, especially in the biotechnology industry.[9] But these firms are cautious investors and "plan for exit."[10] And when examining

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[4] 788 F.3d 1371 (Fed. Cir. 2015), *petition for rehearing en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015).

[5] 915 F.3d 743 (Fed. Cir. 2019), *petition for rehearing en banc denied*, 927 F.3d 1333 (Fed. Cir. 2019).

[6] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (per curiam) (Moore, J., dissenting from the denial of rehearing en banc); *see id.* at 1354 ("We have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible. That per se rule is 'too broad an interpretation of this exclusionary principle [which] could eviscerate patent law.'" (quoting *Mayo*, 566 U.S. at 71)) (alteration in original); *see* Illumina, Inc. v. Ariosa Diagnostics, Inc., 952 F.3d 1367, 1371 (Fed. Cir. 2020) ("Under *Mayo*, we have consistently held diagnostic claims unpatentable as directed to ineligible subject matter.").

[7] *See* John Liddicoat et al., *The Effects of* Myriad *and* Mayo *on Molecular-Test Development in the United States and Europe: Interviews from the Frontline*, 22 VAND. J. ENT. & TECH. L. 785, 800 (2020) ("[D]iagnostic executives estimate the cost to fully develop a test, including clinical education, [to be] between $20.1 and $106 million in the United States alone.").

[8] *See* Dirk Czarnitzki & Andrew A. Toole, *Patent Protection, Market Uncertainty, and R&D Investment*, 93 REV. ECON. & STAT. 147, 157 (2011) ("Our results show that higher levels of uncertainty reduce current R&D investment . . . ."); David J. Kappos & Paul R. Michel, *Supreme Court Patent Decisions Are Stifling Health Care Innovation*, MORNING CONSULT (Oct. 29, 2018, 5:00 P.M.), https://morningconsult.com/opinions/supreme-court-patent-decisions-stifling-health-care-innovation/ (finding that, absent patent protection, "investors are less interested in funding costly new biomarker diagnostic research. As a result, diseases will go undiagnosed, and patients will suffer the consequences").

[9] *See Healthcare Innovation*, NAT'L VENTURE CAP. ASS'N (last accessed Feb. 17, 2021), https://nvca.org/healthcare-innovation/ ("For over three decades, venture capital has spurred the creation and growth of healthcare innovation, such as in the biotechnology and medical device industries. . . . For example, venture capital backed 42% of all FDA-approved drugs from 2009–2018.").

[10] D. Gordon Smith, *The Exit Structure of Venture Capital*, 53 UCLA L. REV. 315, 316 (2005); *see id.* ("The ability to control exit is crucial to the venture capitalist's business model of short-term funding of nascent business opportunities. Exit allows venture capitalists to reallocate funds and the nonfinancial contributions that accompany them to early stage companies.").

potential investment or acquisition targets, venture capitalists view patent protection of a company's intellectual assets as indicative of competent management,[11] ability of the company to survive in a competitive market,[12] and enhanced profitability.[13]

Because VC firms invest so cautiously and with eyes towards exit, it follows that current § 101 jurisprudence may cause VC investors to hesitate in investing in companies developing medical diagnostics technologies that—in light of *Mayo* and its progeny—appear to be patent-ineligible. Decreased investment in medical diagnostics would be concerning from a societal welfare perspective, as "[s]mall venture-backed companies play a critical role in bringing revolutionary medical innovations and discovering groundbreaking treatments and cures aimed at diagnosing, treating, and curing the most deadly and costly diseases."[14]

B. Methodology

To assess the effects of the Supreme Court's jurisprudence on VC investment for diagnostics, I used verified, publicly available VC investment data from the PriceWater Clearinghouse (PwC) MoneyTree tool.[15] Using data from 2006–2010 and 2013–2017, I performed a difference-in-differences (DID) test to compare the change in VC investment amount over time for disease diagnosis technologies compared to all other areas of investment. I employed the DID method because, as compared to other analytical methods which may merely indicate a correlation between variables, the results of a DID test

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11 *See* Ronald J. Mann & Thomas W. Sager, *Patents, Venture Capital, and Software Start-ups*, 36 RSCH. POL'Y 193, 200 (2007) (noting that this assertion likewise holds for a start-up company's "prospect of patents").

12 *See id.* ("Most obviously, patents can solve one of the most difficult problems for a startup: convincing the venture capitalist that the startup can sustainably differentiate itself from its competitors.").

13 *See* Stuart J. H. Graham & Ted Sichelman, *Why Do Start-Ups Patent*, 23 BERKELEY TECH. L.J. 1063, 1078 (2008) ("[P]atents . . . are indicators of a company's ability to maintain supernormal profits or to reduce licensing costs.").

14 *Healthcare Innovation*, *supra* note 9.

15 *See PwC Moneytree*, PRICEWATER CLEARINGHOUSE (2020), https://www.pwc.com/us/en/industries/technology/moneytree.html (reporting venture capital investment dollars according to industry, round, and deals per fiscal quarter). PwC verifies data "via (1) various federal and state regulatory filings; (2) direct confirmation with firm or investor; (3) press release; or (4) credible media sources." *MoneyTree™ Definitions: Report Methodology*, PRICEWATER CLEARINGHOUSE (2020), https://www.pwc.com/us/en/industries/technology/moneytree/moneytree-definitions.html/.

demonstrate causation.[16] Additionally, DID inherently "[a]ccounts for change/change due to factors other than [the] intervention."[17] I used the statistical analysis software, R, to conduct this test.

My analysis excluded data from 2011–2012 because, given that *Bilski* was decided in 2010 and *Mayo* was decided in 2012, VC investment decisions during that period would not have been affected by both *Bilski* and *Mayo*. Likewise, because the Court decided *Mayo* in 2012, its effects on VC investment may not be seen in full force until the following calendar year.

C. Findings

I calculated the DID statistic through two avenues: manually and through an ordinary least-squares (OLS) regression. The coefficient estimate of the interaction between the treatment (change in § 101 jurisprudence) on the treated group (investment levels in disease diagnosis technologies) matched the manually calculated value.[18] Further, the regression data indicated that the negative relationship between *Mayo* and VC investment in medical diagnostics is statistically significant.[19] My study's key finding is that, in the four years following *Mayo*, investment in disease diagnostic technologies was nearly **$9.3 billion** dollars lower than it would have been absent *Mayo*.

However, it is important to note that the yearly VC investment totals for disease diagnostic technologies have generally increased in the years following *Mayo*—but at a lower rate compared to all other industries. Thus, another way to conceptualize the data is that VC investment for all technologies increased much more than the increase in investment for disease diagnostic technologies over the time period analyzed.

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16 *See Difference-in-Difference Estimation*, COLUMBIA PUB. HEALTH: POPULATION HEALTH METHODS (last updated 2:27 PM, Nov. 23, 2020), https://www.publichealth.columbia.edu/research/population-health-methods/difference-difference-estimation ("DID is a quasi-experimental design that makes use of longitudinal data from treatment and control groups to obtain an appropriate counterfactual to estimate a causal effect.").

17 *Id.*

18 The coefficient estimate equaled $-9.286e^{9}$.

19 The relationship was statistically significant, $p = 2.82e^{-14}$, $R^2 = 0.9$.

Conclusion

The confusing, inconsistent interpretations of § 101 and the judicial exclusions to patent eligibility have created an environment where new, useful, and nonobvious medical diagnostics have been unable to obtain patent protection. Consequently, venture capital investors have less incentive to invest in R&D for medical diagnostics. Considering the potential impact of this decreased incentive on public health—*e.g.*, development of fewer diagnostics for rarer diseases and conditions—I support Congressional efforts to amend § 101 and restore patent eligibility for medical diagnostics.

Thank you for your attention.

Sincerely,

A. Sasha Hoyt