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Will There Be a Legislative Push to Reform Patent Eligibility Requirements During the Biden Administration?

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On March 5, 2021, bipartisan members of the Senate Committee on the Judiciary Subcommittee on Intellectual Property, Senators Tillis (R-NC), Hirono (D-HI), Cotton (R-AR) and Coons (D-DE), sent a letter to the USPTO's Commissioner for Patents¹ "regarding the state of patent eligibility jurisprudence in the United States," writing that "since the Supreme Court's landmark decisions in *Alice Corp. v. CLS Bank International and Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, there has been a lack of consistency and clarity in our nation's patent eligibility laws."²

The senators appear to be echoing the sentiment of many intellectual property stakeholders who have opined for years that the *Alice/Mayo* framework has created considerable uncertainty over the fundamental question of what subject matter can and cannot be patented in the United States, thus reducing incentives to invest and innovate in subject matter typically subject to eligibility scrutiny, and negatively impacting the overall competitiveness of American industries. In particular, the *Alice/Mayo* framework has created uncertainty in the computer technology and biotechnology industries as to whether innovations in medical diagnostics, personalized medicine, methods of treatment, computer software, and artificial intelligence are patent-eligible. In fact, the senators remark that in the midst of the COVID-19 pandemic it is "simply astounding" that "current jurisprudence makes it virtually impossible to obtain many patents in the diagnostic methods and precision medicine sectors" and "[t]he lack of clarity has not only discouraged investment in critical emerging technologies, but also led the courts to foreclose protection entirely for certain important inventions in the diagnostics, biopharmaceutical, and life sciences industries."³

The senators urge the USPTO "[t]o assist us as we consider what legislative action should be taken to reform our eligibility laws," requesting, among other things, "information on the current state of patent eligibility jurisprudence in the United States," and a "detailed summary of your findings. . . . no later than March 5, 2022."⁴ The senators state they "are particularly interested in learning how the current jurisprudence has adversely impacted investment and innovation in critical technologies like quantum computing, artificial intelligence, precision medicine, diagnostic methods, and pharmaceutical treatments."⁵

Congress has various options available to it regarding the state of patent eligibility jurisprudence. If the current state of patent eligibility jurisprudence is determined unacceptable from the detailed summary of findings, then

Congress may take action to reform the patent eligibility jurisprudence (e.g., expressly overrule the creation of the judicial exceptions, de-emphasize or completely abolish Section 101 of the Patent Act⁶, or the like). Alternatively, if the current patent eligibility jurisprudence is determined acceptable, then no action may be taken and Congress may leave patent eligibility jurisprudence up to the judiciary. On the legislative front, in April 2019, Senators Tillis and Coons along with Representatives Collins (R-GA-9), Johnson (D-GA-4) and Stivers (R-OH-15) “released a bipartisan, bicameral framework on Section 101 patent reform.”⁷ Hearings were convened to address the issue of patent eligibility, but ultimately, the legislative efforts fizzled. Notably, on the judicial side, in January 2020 the Supreme Court denied patent-eligible subject matter petitions for a writ of certiorari in five cases, including *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*⁸ and *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*⁹ In December 2020, the Supreme Court was once again presented with a petition for a writ of certiorari raising the question of patent eligibility of diagnostic methods in *Ariosa Diagnostics, Inc. v. Illumina, Inc.*¹⁰ On February 16, 2021, a Response was requested by the Court which is due on April 19, 2021.¹¹

Will the USPTO’s response to the senators’ request be a step toward legislative action to reform patent eligibility requirements or will the Supreme Court be left to take up the issue? Only time will tell; however, if you are an intellectual property stakeholder affected by the *Alice/Mayo* framework, now may be the time to have your voice heard once the USPTO publishes its request for information on the current state of patent eligibility jurisprudence. Please, contact the authors with any questions, and stay tuned for updates regarding this important topic.

Footnotes

[1] Currently performing the functions and duties of the Director of the USPTO following Director Iancu’s resignation.

[2] See Letter from Thom Tillis, Mazie Hirono, Tom Cotton & Christopher A. Coons, Sens., U.S. Senate, to Drew Hirshfeld, Comm’r for Pats., U.S. Pat. & Trademark Off. 1 (Mar. 5, 2021) [hereinafter Letter from Sens.], <https://www.tillis.senate.gov/services/files/04D9DCF2-B699-41AC-BE62-9DCA9460EDDA>; see also *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208 (2014); *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66 (2012).

[3] Letter from Sens., supra note 2.

[4] *Id.* 1-2.

[5] *Id.* at 2.

[6] 35 U.S.C. § 101.

[7] See Press Release, Thom Tillis, Sen., U.S. Senate, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework (Apr. 17, 2019), <https://www.tillis.senate.gov/2019/4/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework>.

[8] 140 S. Ct. 855 (2020).

[9] 140 S. Ct. 911 (2020).

[10] Petition for Writ of Certiorari, *Ariosa Diagnostics, Inc. v. Illumina, Inc.*, No. 20-892 (U.S. Dec. 30, 2020), https://www.supremecourt.gov/DocketPDF/20/20-892/165010/20201230142207902_Ariosa%20Diagnostics%20Inc.%20v.%20Illumina%20Inc.%20--%20cert.%20petition.pdf.

[11] See *Docket No. 20-892*, Supreme Ct. of the U.S., 1 <https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/20-892.html> (last visited Mar. 11, 2021).