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Axinn IP Update: SCOTUS Passes on Refining Subject Matter Eligibility Doctrine

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January 13, 2020
By: Thomas Hedemann
Axinn Update

The Supreme Court this morning denied certiorari in five cases addressing Section 101 issues, including the closely watched *Hikma Pharm. USA, Inc., v. Vanda Pharm. Inc.*, No. 18-817, and *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, No. 19-430, involving the patent eligibility of methods of medical treatment and diagnosis, respectively. Two other cases addressed whether patent eligibility is a pure question of law or also involves questions of fact that may prevent resolution of subject matter challenges early in a case: *HP, Inc. v. Berkheimer*, No. 18-415, and *Garmin USA, Inc. v. Cellspin Soft, Inc.*, No. 19-400. These denials signal that the Supreme Court is content with the *Mayo/Alice* framework for now, and that it will be up to Congress to make any significant changes as to how subject matter eligibility is determined.

The Office of the Solicitor General had urged the Court to use *Athena* to clarify the current two-step framework for subject matter eligibility articulated in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), and *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014), arguing that the Court should deemphasize the three specific exceptions to eligible subject matter – laws of nature, natural phenomena, and abstract ideas – and instead refocus the Section 101 analysis on the statutory text and historical context.[1] The Office of the Solicitor General also cautioned the Court against reviewing *Berkheimer* prior to clarifying the substantive Section 101 standards.

The denial of certiorari in *Hikma* may mean that many method of treatment claims will continue to be held patent eligible as not "directed to" a law of nature or natural phenomenon under step one of the *Mayo/Alice* framework. Conversely, the denial in the *Athena* case may mean that many medical diagnostic claims based on the discovery of an association between a biomarker and a medical condition will continue to be held patent ineligible. The denial in *Berkheimer* indicates that patentees will continue to be able to raise factual issues in response to patent eligibility challenges asserted in motions to dismiss or early motions for summary judgment.

The Court had also scheduled a sixth Section 101 case – *Morris Reese v. Sprint Nextel Corp.*, No. 19-597 – for conference with the five other cases but requested a response to Morris Reese's supplemental brief on Friday last week. This case addresses whether the "abstract idea" exception to patent eligibility requires clarity under step one of the *Mayo/Alice* framework. The supplemental brief called attention to the Solicitor General's views referenced above and requested that the Court hold its decision until concluding its review of *Athena*. The requested response is due February 7, 2020.

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[1] *See* Brief for the United States as Amicus Curiae, *Hikma Pharm. USA Inc. v. Vanda Pharm. Inc.*, No. 18-817 (Dec. 6, 2019); Brief for the United States as Amicus Curiae, *HP Inc. v. Berkheimer*, No. 18-415 (Dec. 6, 2019).

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