Huh and Crane in IP Watchdog: PERA – Where Patent Law and Healthcare Issues Collide

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Haynes Boone Partner **Gregory Huh** and Counsel **Sharon Crane** authored an article for *IP Watchdog* exploring the Patent Eligibility Restoration Act (PERA) and the intersection of patent law and healthcare innovation.

They analyze how the proposed legislation could reshape patent protections for diagnostics, gene-based technologies and medical treatments in the United States, bringing U.S. standards closer to those of Europe and other global jurisdictions.

Read an excerpt below.

U.S. Supreme Court opinions in Mayo Collaborative Services v. Prometheus Laboratories, Inc., Association for Molecular Pathology v. Myriad Genetics, Inc., and Alice Corporation Pty. Ltd. V. CLS Bank International et al., produced significant challenges to and unpredictability in obtaining and enforcing patent protection in areas including precision medicine, diagnostics, AI and pharmaceutical treatments. The Patent Eligibility Restoration Act of 2025 (PERA), S. 1546 and the identical H.R. 3152, seek to address these challenges by rewriting 35 U.S.C. § 101 to eliminate all of these "judicial exceptions to patent eligibility." The stakes are particularly high in the life sciences, where U.S. courts have invalidated diagnostic and gene claims of the kind protected abroad. …

Takeaways

- *Diagnostics need jurisdiction-specific claim strategies. An in vitro test that fails under Mayo may be patentable at the EPO but, as a diagnostic method, not in China. Foreign filings should add device, reagent and kit claims and, for China, claims to obtaining intermediate information, which CNIPA's Guidelines do not treat as diagnosis (pt. II, ch. 1, § 4.3.1.2).*
- *Natural-product inventions face the sharpest change. PERA would make isolation enough for natural materials, departing from ChromaDex, but not for human genes. Specifications should document both the human-made alterations PERA would credit and the markedly different characteristics current law requires.*
- *Treatment claims remain a U.S. advantage. 35 U.S.C. § 287(c) limits only remedies against medical practitioners, whereas Europe and China exclude treatment methods. One invention can be claimed as a U.S. treatment method, a medical-use product under EPC art. 54(4)-(5) and a Swiss-type use claim in China.*

Read the full *IP Watchdog* article **here**.

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