United States Patent and Trademark Office

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

MEMORANDUM

To: All PTAB Users

From: John A. Squires
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Subject: Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings

Date: March 11, 2026

In setting forth standards for instituting *inter partes* review ("IPR") and post-grant review ("PGR"), the America Invents Act ("AIA") requires that the Director consider the effect of these standards on the "economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings." *See* 35 U.S.C. §§ 316(b), 326(b).

Over the past several decades, substantial segments of the United States's existing manufacturing base—particularly in the electronics and computer industries—have moved overseas. Further, several recent studies by the Departments of Commerce and Homeland Security have highlighted the significant economic and national security damage this trend has caused, including its threat to America's innovation leadership. *See, e.g.*, Bureau of Industry and Security, *Assessment of the Status of the Microelectronics Industrial Base in the United States* (2023); Department of Commerce and Department of Homeland Security, *Assessment of the Critical Supply Chains Supporting the U.S. Information and Communications Technology Industry* (Feb. 24, 2022). These developments bear directly on the Director's statutory obligation to consider the effect of institution standards on the economy and the integrity of the patent system.

Soleno Therapeutics, Inc.
Exhibit 2030
Apotex v. Soleno
PGR2026-00034
Ex. 2030-001

Some stakeholders have asserted that the availability of IPRs and PGRs is important to protect American manufacturers and small businesses. However, the off-shoring trends discussed above have continued, notwithstanding the broad availability of IPR and PGR proceedings for fifteen years. Moreover, many of the most frequent users of IPR and PGR proceedings are large companies that have stated in public financial disclosures that they do not have a significant, existing manufacturing presence in the United States, nor are they taking concrete steps to invest in American manufacturing. *See* U.S. Patent and Trademark Office, *Study of High-Volume Filers and Domestic University-Related Patentees in District Court Litigation at the PTAB* (Oct. 2025) (identifying the most frequent IPR petitioners). These facts and data raise a legitimate question about whether the current institution framework appropriately weighs the interests of entities that invest in domestic production.

To assist the Office in gathering data about the extent to which AIA proceedings give a tactical advantage to companies that neither manufacture in the United States, nor are making American manufacturing investment, the Office encourages parties to identify relevant facts in their discretionary briefing. The Office also encourages petitioners who are small businesses that have been sued for infringement to identify themselves to assist the Office in understanding how frequently small businesses use IPRs and PGRs to defend against claims of infringement.

When determining whether to institute IPR and PGR proceedings, the Director will consider:

(1) the extent to which any products accused of infringement in a parallel proceeding are manufactured in the United States or are related to investments in American manufacturing operations;

(2) the extent to which any products made, sold, or licensed by the patent owner that compete with the accused products are manufactured in the United States; and

(3) whether the petitioner is a small business that has been sued for infringement of the patent at issue.

In evaluating the extent of manufacturing or manufacturing investments in the United States, the Director will consider, and parties should address, not only assembly of the final product in the United

States, but also the extent to which components of a product are made in the United States and the extent to which products made in the United States are sent for further processing outside the United States. In the case of method claims, the relevant products for the purposes of this memo are the devices used to carry out the method. For example, for claims directed to a method of operating a computer, the relevant product would be the computer.

In determining whether a petitioner is a small business that has been sued for infringement, the Director will consider all relevant facts that the parties raise, including the Small Business Administration's size standards set forth in 13 C.F.R. §§ 121.801 through 121.805 and 37 C.F.R § 1.27(a) that would render a person, business, or nonprofit organization eligible for reduced patent fees.

This Memorandum applies to all IPRs and PGRs in which the due date for a patent owner discretionary brief has not yet elapsed.