Senate Committee Advances PREVAIL Act

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In a tight 11-10 vote, the Senate Judiciary Committee approved the PREVAIL Act (Promoting and Respecting Economically Vital American Innovation Leadership Act) that would make substantial changes to Patent Trial and Appeal Board (PTAB) proceedings. The bill addresses perceived anti-patentee imbalances in the current inter partes review (IPR) system. However, a number of Senators raised concerns and were seeking assurances about a negative impact on generic drug prices. The Bill as adopted by the Judiciary Committee included a friendly amendment by the Bill's co-sponsor Sen. Coons that attempted to address some of the drug-pricing concerns by expanding the scope of who can file IPR/PGR petitions. In particular, the original bill allowed only those sued or accused of infringement to challenge patents. As discussed below, the new approach is designed to enable petitions by generic-drug makers and non-profit patient groups. The major changes in the bill include raising the burden of proof to "clear and convincing evidence," implementing strict timing requirements for PTAB decisions, requiring greater independence of PTAB judges, establishing a "single forum" rule preventing parallel validity challenges, and strengthening estoppel provisions against repeat challenges.

Congressional Findings and Purpose: The bill begins with extensive findings about patent rights and innovation, stating that "reliable and effective patent protection encourages United States inventors to invest their resources in creating new inventions." Congress specifically notes that "unintended consequences of the comprehensive 2011 reform of patent laws have become evident," including "the strategic filing of post-grant review proceedings to depress stock prices and extort settlements" and "filing of repetitive petitions… that have the effect of harassing patent owners."

Key Changes

1. Standing Requirements: The bill adds significant new standing requirements under § 312(a)(6). A petitioner must certify it either:

- "is a nonprofit organization" filing solely to assess patentability;
- "is currently engaging in, or has a bona fide intent to engage in, conduct within the United States that reasonably could be accused of infringing";

- "would have standing to bring a civil action… seeking a declaratory judgment of invalidity"; or
- "has been sued in a court of the United States for infringement"

2. Burden of Proof: Under new § 316(e), "the presumption of validity under section 282(a) shall apply" and "the petitioner shall have the burden of proving a proposition of unpatentability of a previously issued claim of a patent by clear and convincing evidence." However, for substitute claims proposed in amendments, the lower "preponderance of the evidence" standard remains.

3. Single Forum and Estoppel: The bill adds § 315(c)(1) preventing parallel validity challenges: "If an inter partes review is instituted challenging the validity of a patent, the petitioner, a real party in interest, or a privy of the petitioner may not file or maintain, in a civil action . . . or in a proceeding before the International Trade Commission . . . a claim, counterclaim, or affirmative defense challenging the validity of any claim of the patent."

4. Panel Constitution and Independence: New § 6(d) requires documentation of panel changes and restricts communications: "An officer who has supervisory authority… shall refrain from communications with the panel that direct or otherwise influence any merits decision." Additionally, "a member of the Patent Trial and Appeal Board who participates in the decision to institute… shall be ineligible to hear the review."

5. Procedural Timing Requirements: The bill imposes strict timing requirements:

- 45 days for institution rehearings (§ 314(e))
- 90 days for final written decision rehearings (§ 318(e))
- 120 days for decisions on remand (§ 319(b))
- 60 days to issue trial certificates after appeals conclude (§ 318(b))

Senator Ted Cruz proposed an amendment that was not adopted — His amendment would have protected "independent inventors" from PTAB challenges via an opt-out provision. The core of the amendment states that "The Director shall dismiss a petition filed under section 311 to institute an inter partes review . . . if the patent owner of the applicable patent is an independent inventor, unless the patent owner consents to the inter partes review being instituted."

The amendment carefully defined who qualifies as an "independent inventor" through several criteria. First, the patent owner must be "an inventor named on the patent (or an entity controlled by such an inventor)" and must have "the authority to enforce the patent or otherwise settle an outstanding dispute." For entities, they must meet the USPTO's small entity size standards.

Most notably, the Cruz amendment would impose an income cap, requiring that the inventor or entity "had a gross income for the most recently completed calendar year (including amounts from sales of products and services) that is not more than 100 times more than the gross income required to satisfy" the micro entity status. Micro entity income limit is 3x median household income ($80.6 thousand for 2023). $80,600 x 3 x 100 = $24 million income limit — applied collectively to "the patent owner and all inventors listed on the patent." At the hearing, other Senators expressed support for the general idea, but thought that $24 million in annual income was too high of a cap.