AIPLA

American Intellectual Property Law Association

June 3, 2026

The Honorable Darrell Issa
Chair
Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Committee on the Judiciary
U.S. House of Representatives
2108 Rayburn House Office Building
Washington, DC 20515

The Honorable Hank Johnson
Ranking Member
Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Committee on the Judiciary
U.S. House of Representatives
2240 Rayburn House Office Building
Washington, DC 20515

RE: AIPLA Views on H.R. 3269, the "ETHIC Act," and H.R. 6485, the "Skinny Labels, Big Savings Act"

Dear Chair Issa and Ranking Member Johnson:

The American Intellectual Property Law Association (AIPLA) appreciates the Subcommittee's continued attention to issues at the intersection of patent law, pharmaceutical competition, and innovation policy. We write to provide AIPLA's views regarding H.R. 3269, the "Eliminating Thickets to Increase Competition Act" or the "ETHIC Act," and H.R. 6485, the "Skinny Labels, Big Savings Act."

AIPLA is a national bar association of approximately 6,500 members including professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

AIPLA recognizes and appreciates Congress's interest in promoting competition and access to affordable medicines. At the same time, AIPLA believes changes to patent enforcement frameworks should be carefully calibrated to preserve the incentives and technology-neutral principles underlying the U.S. patent system and to avoid unintended consequences for innovation, investment, and established patent doctrines. As such, we have concerns about both legislative bills.

With respect to H.R. 3269, we are concerned that the bill would impose field-specific limitations on patent enforcement by restricting patent owners to asserting only one patent per "Patent Group" against certain pharmaceutical and biologic applicants and related parties. As drafted, the bill would use terminal disclaimers filed under 35 U.S.C. § 253 as the basis for limiting enforcement

of otherwise valid patents, despite the fact that terminal disclaimers are a prosecution tool routinely used across all fields of technology to address obviousness-type double patenting and align expiration dates.

AIPLA is further concerned that the bill may distort patent prosecution practices and undermine enforcement of distinct inventions that the U.S. Patent and Trademark Office itself may have required applicants to pursue separately through restriction practice. Existing statutory and judicial mechanisms already address concerns relating to the assertion of multiple patents in pharmaceutical litigation, including the Hatch-Waxman Act, the Biologics Price Competition and Innovation Act, obviousness-type double patenting doctrine, claim preclusion principles, and case management authority under the Federal Rules of Civil Procedure. AIPLA believes these existing frameworks remain the more appropriate mechanisms for addressing such concerns. Lastly, the bill would eliminate enforcement of presumptively valid patents at the outset of litigation, without any adjudication of merits.

With respect to H.R. 6485, AIPLA is concerned that the bill would create a categorical safe harbor from direct, induced, and contributory infringement liability for certain conduct relating to method-of-use patents involving pharmaceutical and biologic products. Current inducement and contributory infringement analyses under 35 U.S.C. § 271(b) and (c) are based on a totality-of-the-circumstances framework that permits courts to evaluate both labeling and other relevant evidence on a case-by-case basis, which we believe to be the appropriate analysis.

AIPLA also believes the proposed legislation would depart from that longstanding technology-specific framework, consistent with Article 27(1) of the TRIPS Agreement, by creating industry-specific exclusions from infringement liability and by categorically excluding certain forms of evidence from consideration. Existing Hatch-Waxman carve-out procedures already permit generic applicants to omit patented indications from approved labeling while preserving a patent owner's ability to pursue remedies where conduct induces infringement of patented uses. AIPLA believes the current framework appropriately balances the interests of innovation and competition without requiring categorical statutory exemptions.

AIPLA also notes concerns regarding the retroactive application provisions included in H.R. 6485, which would apply substantive changes to infringement liability to conduct occurring before enactment and to pending proceedings.

AIPLA appreciates the Subcommittee's continued engagement on these important issues and we thank you in advance for considering our views. We stand ready to serve as a resource to the Committee and its staff as consideration of these matters continues.

Very truly yours,

Salvatore Anastasi
President
American Intellectual Property Law Association