March 14, 2024

The Honorable Richard J. Durbin
Senate Judiciary Committee Chairman
224 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Lindsey Graham
Senate Judiciary Committee Ranking Member
224 Dirksen Senate Office Building
Washington, D.C. 20510

To Chairman Durbin and Ranking Member Graham:

On behalf of the manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines, the Association for Accessible Medicines (AAM) writes to ***oppose S. 2220, the PREVAIL Act***, introduced in the U.S. Senate on July 10, 2023. While AAM applauds Congress's efforts to promote "reliable and effective patent protections,"[1] the PREVAIL Act undermines the very purpose of IPR, which Congress created "to enable early challenges" to "patents that should not have issued."[2] More importantly, the Act will result in higher drug prices for patients. Indeed, IPR has been a critical pathway for generic and biosimilar companies to challenge wrongly-issued patents and enable the market entry of lower-cost drugs,[3] but this option would diminish under the PREVAIL Act. Over the past ten years, generic and biosimilar drugs have saved patients and payers $2.9 trillion,[4] and between 2015-2019 alone, the "delayed entry of biosimilars due to patenting has cost the U.S. health care system an astounding $7.6 billion in lost savings."[5] While AAM opposes the PREVAIL Act as a whole, AAM briefly addresses the most problematic provisions of the Act below.

The Prevail Act Precludes Generic and Biosimilar Companies from Filing Early IPR Challenges on Patents That Block Competition

The PREVAIL Act includes a prohibitive standing requirement, making it a "necessary condition[]" that an entity must be sued or charged with infringement before filing a petition for IPR.[6] This provision would prevent timely IPR challenges of pharmaceutical patents, and would chill the feasibility of such IPR challenges altogether.

Developing a generic or biosimilar product presents unique issues that make early IPR challenges immensely important. Long before generic and biosimilar companies seek FDA approval—and thus long before they are sued for infringement—they often know which patents they must clear to enter the market. For example, by statute, brand-name drug holders must list in the Orange Book the patents they believe could reasonably be asserted against an unauthorized user.[7] But the "continued existence"

[1] PREVAIL Act, S. 2220, 118th Cong. § 2 (2023).

[2] H.R. Rep. 112-98, at 39-40, 47-48 (2011).

[3] *See, e.g.*, AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 ('STRONGER')," at 2-3 (Sept. 11, 2019), *available at* https://accessiblemeds.org/sites/default/files/2019-09/AAM-SJC-STRONGER-Patents-Act-Statement-9-11-19.pdf.

[4] AAM, The U.S. Generic & Biosimilar Medicines Saving Report, Sept. 2023, at 3, 7, https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[5] Biosimilar Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients: Part I* (June 2019), *available at* https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf.

[6] PREVAIL Act, S. 2220, 118th Cong. § 4 (2023).

[7] *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b)(1), (c)(2), (e).

of a weak patent blocking market entry "can disrupt product development . . . for years,"[8] and without early patent challenges, there would be "a major distortion in research spending" by drug developers that "attempt[] to innovate around [a] wrongly issued patent."[9] Given the considerable resources needed to develop a biosimilar drug, "[a] number of Biosimilars have turned to *inter partes* review ('IPR') proceedings to challenge the validity of patents that may cover their proposed biosimilar products or processes prior to submission of their biosimilar applications to FDA."[10]

Waiting for a patent infringement suit poses another problem: the risk of discretionary denials. Under *Fintiv*, the Board may discretionarily deny petitions based on the progress of parallel litigation proceedings, including the proximity of the court's trial date to the Board's projected final written decision date.[11] Given the statutory 30-month stay of FDA approval on ANDA products,[12] there is likely always close proximity between a district court trial date and the anticipated final written decision date, making it highly likely that petitions filed after litigation commences will be discretionarily denied.[13]

PREVAIL Precludes Generic and Biosimilar Manufacturers Who Are Sued From Meaningfully Using the IPR Process

The PREVAIL Act's proposal that, absent "exceptional circumstances" subsequent petitions cannot challenge the same patent, uniquely harms generic and biosimilar companies.[14] The Hatch-Waxman Act and Biologics Price Competition and Innovation Act (BPCIA) make it highly likely that multiple generic and biosimilar companies will be interested in invalidating the same patents, though not always at the same time, particularly where companies are at different stages of product development. With multiple companies interested in challenging the same patents, there are numerous circumstances in which a subsequently-filed petition may be warranted. For example, the subsequent petitioner may be unrelated to the original petitioner and wish to frame its arguments differently than the original petitioner.[15] As another example, a subsequent petitioner may be more concerned with different claims than the first petitioner. The PREVAIL Act improperly impedes the IPR pathway for such subsequent petitioners, forcing these companies to defer to the arguments presented by their competitors.

PREVAIL Prevents the PTO From Correcting its Own Mistakes

Finally, the PREVAIL Act's proposal to heighten the burden of proof to clear and convincing evidence ignores Congress's rationale for creating IPR: to address ***wrongly-issued*** patents, not properly-issued ones.[16] Recognizing that "questionable patents are too easily obtained and are too difficult to challenge," Congress created IPR to "provid[e] a more efficient system for challenging patents that should not have issued."[17] Heightening the burden of proof to clear and convincing evidence would undermine the entire premise for IPR, making such wrongly-issued patents just as "difficult to challenge" as properly-issued ones.[18]

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[8] Joe Matal, A Guide to the Legislative History of the America Invents Act: Part II of II, 21 Fed. Cir. B. J. 539, 600 (2012).

[9] Dean Baker, The Impact of Exempting the Pharmaceutical Industry from Patent Reviews, Ctr. for Econ. & Pol. Res. 10 (July 2015)

[10] AAPS, Biosimilars ,Regulatory, Clinical, and Biopharmaceutical Development, 98-99 (Hiten J. Gutka et al., eds. 2018).

[11] *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper No. 11, at 5-6 (P.T.A.B. Mar. 20, 2020)

[12] 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. 271(e)(2)(A).

[13] *See, e.g.*, Lex Machina, Hatch-Waxman / ANDA Litigation Report at Fig. 9 (2018) (showing that trial for Hatch-Waxman cases occurred at a median of 731 days and 795 days after the complaint in the Districts of Delaware and New Jersey, respectively).

[14] PREVAIL Act, S. 2220, 118th Cong. § 4 (2023).

[15] *See, e.g.*, *Pfizer Inc. v. Biogen, Inc.*, IPR2018-00186, Paper 15 at 17-20 (P.T.A.B. June 14, 2018) (instituting review of a subsequent petition, despite some overlap with a prior petition).

[16] PREVAIL Act, S. 2220, 118th Cong. § 4 (2023).

[17] H.R. Rep. No. 112–98, at 39-40 (2011).

[18] *See id.*

PREVAIL's "Single Forum" Provision Will Delay Generic Entry

The PREVAIL Act's single forum provision ignores the importance of parallel district court proceedings due to the Hatch-Waxman Act.[19] Under the Hatch-Waxman Act, a patentee's timely filing of a patent infringement complaint results in a 30-month stay on the approval of the Abbreviated New Drug Application (ANDA).[20] Importantly, this stay can be terminated, including through a district court judgment "that the [asserted] patent is invalid or not infringed."[21] Terminating the 30-month stay enables generic drugs to enter the market sooner than the statute would otherwise allow.

Critically, the 30-month stay of approval does ***not*** terminate upon obtaining a favorable ruling in IPR.[22] Thus, while IPR is an important and valuable pathway for generic companies to challenge weak patents, it is often necessary for such companies to also rely on district court proceedings to terminate the 30-month stay. Precluding generic companies from relying on parallel district court proceedings would unnecessarily prevent proper terminations of the 30-month stay and delay the entry of lower-cost drugs.

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As always, AAM supports a strong and robust patent system to encourage and enable innovation. However, low-quality patents sometimes issue despite the Office's best efforts, making IPR a critical vehicle for challenging these patents. Because the PREVAIL Act diminishes the viability of IPR challenges and disproportionately harms generic and biosimilar companies, AAM and its member companies strongly oppose S. 2220, the PREVAIL Act.

Sincerely,

David Gaugh, R.Ph.
Interim President & CEO

cc: Sen. Christopher Coons
Sen. Thomas Tillis
Sen. Mazie K. Hirono

[19] PREVAIL Act, S. 2220, 118th Cong. § 4 (2023).
[20] 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. 271(e)(2)(A).
[21] 21 U.S.C. § 355(j)(5)(B)(iii)(I).
[22] *See* 21 U.S.C. § 355(j)(5)(B)(iii).