July 25, 2024

The Honorable Chuck Schumer
Senate Majority Leader
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Senate Minority Leader
317 Russell Senate Office Building
Washington, DC 20510

To Majority Leader Schumer and Minority Leader McConnell:

On behalf of the manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines, the Association for Accessible Medicines and its Biosimilars Council (collectively, "AAM") writes to ***oppose S. 142, the Preserve Access to Affordable Generics and Biosimilars Act*** ("the Act") and to urge you to object to any efforts to advance the bill on the Senate floor, whether independently or in a legislative package.

Our objections are based on both constitutional and prudential concerns. First, as detailed below, the Act is facially unconstitutional under the recent Supreme Court *Jarkesy* decision. Second, the Act would raise the price of prescription drugs by severely restricting the ability of generic and biosimilar manufacturers to enter into patent settlement agreements and reducing generic and biosimilar competition.

S. 142 is Unconstitutional Under Recent Supreme Court Precedent

As a threshold matter, S. 142 is unconstitutional and, if enacted, will almost certainly be set aside by a court because its entire remedial structure is contrary to the Seventh Amendment.

As recently articulated by the U.S. Supreme Court in *SEC v. Jarkesy*, 144 S. Ct. 2117 (2024), the Seventh Amendment protects the right to a jury trial in federal court. S. 142 is plainly inconsistent with *Jarkesy*. The bill expressly provides for the FTC to obtain civil penalties—the exact type of claims the Supreme Court held are subject to Seventh Amendment protections—without a jury trial at any step of the process. Rather, the bill is structured so that liability is fully determined in an administrative proceeding with an ALJ and without a jury, with "conclusive" factual findings made by that ALJ. Then, in a follow-on action in court to impose civil penalties, the liability findings made by the ALJ are treated as "conclusive" and a judge, not a jury, assesses penalties in a ***bench*** trial. *See* S. 142, § 27(e)(3) ("In determining the amount of the civil penalty described in this section, ***the court*** shall take into account . . . .").

S. 142 is unconstitutional under *Jarkesy* for at least two independent reasons. First, S. 142 takes removes the jury entirely from both steps of its delineated process for assessing civil monetary penalties. Second, by having an ALJ "conclusively" determine liability – without a jury – it impermissibly takes away from the jury its core function of finding facts. Just as it is unconstitutional to side-step the jury in an action seeking civil penalties for fraud (as in *Jarkesy*), so too is it impermissible in an action seeking civil penalties for unfair competition. Both types of claims are analogous to common-law claims

that fall squarely within the scope of Seventh Amendment protections.

Following *Jarkesy*, Supreme Court precedent precludes agencies from imposing civil penalties on their own for perceived statutory violations like those created here. Congress cannot now strip away those constitutional rights.

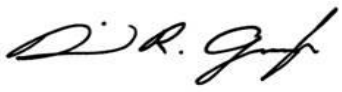
S. 142 will Lead to Higher Prescription Drug Prices

From a policy perspective, S. 142 will result in fewer patent challenges to expensive brand-name patent thickets. Challenging potentially non-innovative patents is an expensive, time-consuming endeavor without any guarantee of success. Moreover, "patent thickets" on brand-name drugs cannot be overcome in a single patent litigation. A prominent example is Humira® – the top-selling prescription drug in America – which is protected by a fortress of 136 patents through 2034. The only reason that there are currently biosimilars and interchangeables available on Humira® is patent settlements, which S. 142 seeks to restrict.

S. 142 is also outdated, neglecting important changes to patent settlements driven by the Supreme Court and FTC. The Supreme Court's 2013 decision in *FTC v. Actavis* significantly changed the patent settlement landscape. Settlement agreements with "large, unjustified reverse payments" were determined to be potentially anticompetitive when combined with a market entry date well beyond patent expiry. Since that Supreme Court decision and subsequent FTC actions, the total number of patent settlement agreements has increased (226 in FY17) while the number of potential anticompetitive settlement agreements has declined to only three (~1%), as documented by the FTC.[1] As the Commission stated in its most recent report, "Despite the high number of settlements, those that include the types of reverse payments that are likely to be anticompetitive remain ***very low***." This data undermines the oft-cited but significantly outdated 2010 FTC analysis.

In recent years, AAM and its Biosimilars Council have provided several alternatives and recommended improvements to the Act and similar patent settlement legislation. **Unfortunately there have been no hearings on this bill in this Congress that reflect the new data, nor any consideration of the *Jarkesy* constitutional defect.** AAM and its Biosimilars Council certainly wish to reduce barriers to competition that delay patient access to more affordable medicine. We look forward to working with you to achieve these goals and bring lower-cost medicines to patients.

Sincerely,



David Gaugh, R.Ph.
Interim President & CEO

cc: All Senators

[1] FTC, "Overview of Agreements Filed in FY 2017," December 2020, available at https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf.