

July 8, 2024

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

To Chairman Durbin and Ranking Member Graham:

The Campaign for Sustainable Rx Pricing (CSRxP) is a broad-based coalition of leaders representing physicians, nurses, hospitals, consumers, health plans, pharmacy benefit companies, pharmacists and employers. Our coalition is united behind one goal – to lower the cost of prescription drugs for patients. We support bipartisan, market-based solutions to increase competition, improve patient affordability and enhance list price transparency. We appreciate the many bipartisan measures passed unanimously by the Senate Judiciary Committee to limit abuses of the patent system and address the anti-competitive business tactics used by brand-name pharmaceutical companies to delay competition from more affordable generic and biosimilar medicines.¹

We write today to express our concerns with and opposition to the PREVAIL Act (S. 2220). The PREVAIL Act would undermine the U.S. Patent and Trademark Office's (PTO) capacity to review patentability claims, weaken the inter partes review process, and strengthen brand-name pharmaceutical companies' ability to extend its monopoly protections. The PREVAIL Act would inevitably result in patients paying the high cost of brand-name prescription drugs for longer than even occurs today.

PTO's inter partes review is an important mechanism to ensure patents are awarded for truly novel inventions, with the input of subject matter experts, and in line with Congressional intent. To that end, the Patent Trial and Appeal Board (PTAB) issued a report in March 2023 on petitions challenging Orange Book and biologic patents over the previous 10.5 years.² PTAB's report shows 17% of challenged Orange Book patent claims and 25% of challenged biologic patent claims were found unpatentable by a preponderance of the evidence. This data is evidence that the IPR process does not unfairly disadvantage or harm the ability of brand-name pharmaceutical companies to hold patents.

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¹ CSRxP Press Release, "CSRXP Applauds Senators for Bipartisan Action to Hold Big Pharma Accountable for Egregious Patent Abuse," March 2023.

² U.S. PTO, "PTAB Orange Book patent/biologic patent study: FY23 Q2 Update," March 2023 (Updated June 2023).



When one considers the relative ease and low cost by which brand-name pharmaceutical companies obtain patents in the U.S., it is clear that the status quo favors Big Pharma at the expense of patients and taxpayers. Recent research on pharmaceutical patents concludes:

- "Rather than creating new medicines ... drug companies are focusing their time and effort extending the patent life of old products."³
- Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once."⁴
- "Drugmakers filed more than 140 patent applications on average per drug; on average 66% of patent applications were filed after the FDA approved the drug to be on the market."
- "... the one-year cost of delayed competition from patent thickets is \$1.9 billion for Enbrel, \$2.5 billion Eylea, \$7.6 billion for Humira, \$3.1 billion for Imbruvica, and \$1.8 billion for Opdivo."⁶

We strongly encourage the Senate Judiciary Committee to continue its work to address abuses of the patent system. Advancing the PREVAIL Act would run counter to this work and the recent progress made by Congress. We believe in an appropriate balance between scientific innovation and patient access; however, the PREVAIL Act would only further tip the scales in favor of Big Pharma and its ability to establish and maintain patent thickets.

Thank you for your leadership on bipartisan, market-based solutions to lower the cost of prescriptions drugs. We would be glad to discuss our concerns with the PREVAIL Act in more detail and look forward to continuing to work with you to advance commonsense solutions to increase pharmaceutical competition.

Sincerely,

Lauren Aronson
Executive Director

Campaign for Sustainable Rx Pricing

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³ Feldman, Robin, "May your drug price be evergreen," Journal of Law and Biosciences," December 2018.

⁴ Ibid.

⁵ I-MAK, "Overpatented, Overpriced: Curbing patent abuse: Tackling the root of the drug pricing crisis," September 2022

⁶ Matrix Global Advisors, "Patent Thickets and Lost Drug Savings," January 2023.