Congress of the United States
House of Representatives
Washington, DC 20515–4319

December 5, 2025

The Honorable Howard Lutnick
Secretary of Commerce
1401 Constitution Ave, NW
Washington, D.C. 20230

Dear Secretary Lutnick,

As a bipartisan group of members committed to lowering drug prices, we write to urge the U.S. Department of Commerce to prioritize addressing the issue of patent thickets surrounding branded pharmaceutical products, particularly biologics, as a critical pro-competition reform. Duplicative patent thickets create significant barriers to market entry for biosimilars and generics, delaying access to affordable medications and sustaining high drug prices for patients. By tackling this issue, the Department can foster competition, reduce healthcare costs, and support domestic manufacturing, all in line with the Trump Administration's commitment to promoting a competitive economy and reducing regulatory burdens.

Patent thickets are a strategic tool used by branded pharmaceutical companies to extend market exclusivity beyond the intended scope of patent law. As documented in a study by Goode and Chao,[1] biologic drugs in the U.S. are protected by significantly more patents than in comparable markets like Canada and the United Kingdom. Their analysis of 30 biosimilars found that, on average, nine times more patents are asserted against biosimilars in the U.S. than in Canada, and twelve times more than in the UK. This disparity correlates with delayed biosimilar market entry in the U.S., with an average delay of 34 months from FDA approval to launch, compared to 7.4 months in Canada and 4.7 months in the UK. This means patients are paying more for drugs solely based off pharmaceutical gamesmanship.

In addition, research from Brill and Robinson[2] has shown the top 8 biologics in the U.S. are protected by 41 to 132 patents each. For 20 FDA-approved biosimilars, 279 patents were asserted in the U.S., compared to just 16 in the UK and 1 in Germany. These excessive patents create a costly and time-consuming barrier for biosimilar manufacturers, who face litigation costs of up to $1 million per patent in inter partes review (IPR) proceedings—negatively impacting domestic manufacturing for prescription drugs. A striking example of this practice is a drug to treat Rheumatoid Arthritis. This drug's patent portfolio is comprised of 73 patents, 80% of which are "non-patentably distinct," linked by terminal disclaimers that allow duplicative patents under U.S. Patent and Trademark Office (USPTO) rules. In contrast, the European Union

[1] Goode, R., & Chao, B. (2022). Biological patent thickets and delayed access to biosimilars, an American problem. Journal of Law and the Biosciences. https://doi.org/10.1093/jlb/lsac022

[2] Brill, A., & Robinson, C. (2021). How Patent Thickets Constrain the US Biosimilars Market and Domestic Manufacturing. Matrix Global Advisors.

granted only 8 non-duplicative patents for the same drug. This thicket enabled the branded manufacturer to assert up to 65 patents against a single biosimilar competitor, delaying U.S. market entry until 2023—five years after biosimilars launched in Europe.
Another example is an injectable medication to treat various eye diseases, including Diabetic Retinopathy. The manufacturer of the injectable owns a family of patents that cover the medication's dosing regimen that expires 8 years later than the basic product patent covering the same drug. Twelve of these patents have terminal disclaimers, meaning they assert duplicative, repetitive claims. One patent claims patient improvement by 24 weeks, and the other patent claims patient improvement by 52 weeks.

Accordingly, current patent thicket schemes undermine competitive frameworks that are intended to reduce costs for the patient and the Medicare program as a whole. Additional reforms are necessary to root out these hidden costs and increase domestic competition. To address this issue head on, our Eliminating Thickets to Increase Competition Act (ETHIC) Act would stop these double patenting practices by requiring a branded pharmaceutical manufacturer, during litigation against a biosimilar manufacturer, to choose their preferred patent from each of the patent groups covering a drug to assert. This would allow additional biosimilars and generics to enter the market earlier, which will reduce barriers to patient access to lower-cost medicines.

By addressing this issue in the manner outlined by the ETHIC Act, the Department can advance a pro-competition agenda that lowers drug prices without threatening innovation. The ETHIC Act is in line with the administration's goal of increasing competition and targeting artificial costs in health care. We request the administration's support of this bill, as the President looks to deliver on reducing prescription drug costs.

Sincerely,

Jodey C. Arrington
Member of Congress

Peter Welch
United States Senator

Lloyd Doggett
Member of Congress

August Pfluger
Member of Congress

CC: Andrew Ferguson and Mark Meador, FTC; Jamieson Greer, USTR; Dr. Mehmet Oz, CMS