Congress of the United States
Washington, DC 20515

March 24, 2023

The Honorable Kathi Vidal
Director
United States Patent and Trademark Office
600 Delaney St.
Alexandria, Virginia 22314

Dear Director Vidal:

We write today to express concern regarding the practice known as "patent thicketing," as well as the impact of this practice on competition in the prescription drug market and access to affordable medicines. As you know, branded pharmaceutical manufacturers will often seek numerous patents on a single feature of a drug, creating a dense web, or thicket, of patents that delay generic and biosimilar competition. While some may question the quality of these patents, the high cost, uncertainty, and lengthy process for challenging them makes it practically impossible to sort the good from the bad. Scholars have found that in some instances up to 80% of patents in these "thickets" are non-distinct, or duplicative.[1]

For example, the manufacturer of a blockbuster biological drug was granted separate U.S. patents where the alleged difference in the two patents is:

1. Claims a method of treating rheumatoid arthritis in a human subject using a particular dosage regimen, vs.;
2. Claims a method of reducing signs and symptoms [of rheumatoid arthritis] in a patient using the exact same dosage regimen.[2]

Furthermore, data from a recent peer reviewed study published in the Journal of Law and Biosciences suggests that this practice not only manipulates the U.S. patent system to shield products from scrutiny, but also distorts the market by protecting older, branded drugs from competition.[3] This practice is not isolated to one drug, but rather it is occurring across the costliest drugs on the market[4] and has a devastating impact on U.S. patients and our health care system. Another recent study, which was published in the Journal of Clinical Pharmacology & Therapeutics and analyzed only a single drug, estimated that from 2016-2019 Medicare spent $2.2 billion dollars more on that one drug than if competition had entered as expected.[5]

Delayed entry into the market by generics and biosimilars doesn't just cost the U.S. government and taxpayers more money, it also severely limits patients' cost-effective options for treatment. This is happening across the nation, and millions of Americans have had to make tough decisions as to whether they can afford to continue their medication regimen as prescribed. Too many have been forced to ration

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[1] https://academic.oup.com/jlb/article/9/2/lsac022/6680093
[2] https://vimeo.com/779284029/21d8d96e71
[3] https://academic.oup.com/jlb/article/9/2/lsac022/6680093
[4] https://academic.oup.com/jlb/article/9/2/lsac022/6680093
[5] Lee CC, et al. Clinical Pharmacology and Therapeutics : 18 Jun 2021. Available from: URL: http://doi.org/10.1002/cpt.2322

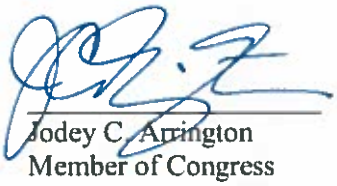
and skip necessary medications altogether—risking their own health and increasing overall costs to the system as complications arise and more expensive medical care becomes necessary.

We believe that the U.S. must protect and reward innovation and incentivize drug manufacturers to continue to invest in research and development to improve the drug after launch. We also understand that such investment is expensive, and manufacturers must recoup the cost to continue to innovate. However, taking steps to restore balance in the U.S. patent system is imperative to ensure a healthy, competitive, free market.

We are dedicated to addressing drug pricing through fair competition and urge you to consider the policies outlined in your October 4, 2022, request for comment, such as requiring a branded manufacturer seeking multiple patents on the same drug feature to admit that the claims rejected for double patenting are not patentably distinct. Such admission would ensure that if one of the duplicates is later found to be invalid, courts may consider that fact as evidence against the others. In other words, non-distinct patent claims could "rise or fall together." This would promote innovation that would improve patient care and end the practice of blocking lower-cost alternatives by stacking duplicative patents on old drugs. By allowing generic and biosimilar competition in the market to compete at an appropriate time, savings can be extended to health systems and patients, whether insured by the commercial market or government programs, while still providing strong incentives for manufacturers to continue to innovate and produce new treatments and cures.

Thank you for your consideration.

Sincerely,



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