U.S. PIRG

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September 18, 2024

Dear Senator,

I am writing to urge you to vote NO on two bills posted for mark-up in the Senate Judiciary committee on Thursday: S.2220 - PREVAIL Act and S 2140 - PERA (Patent Eligibility Restoration Act).

These bills will undermine the progress Congress has made in addressing the high prices of prescription drugs over the last few years. Unfortunately, patients, employers and payers still face many high drug prices.

Although reforms to the patent system are needed, PREVAIL and PERA are not the reforms we need.

An exemplary model of high value health care is the existence of generic and biosimilar drugs. Biosimilar and generic drugs are therapeutically equivalent so there is no loss in quality for patients who chose the lower cost option. But the issue is that too often, because of patent application misuse, there are no alternatives to brand names on the market even years after the original patent has expired.

We know the power of competition to bring down drug prices, especially after a prescription drug patent expires and generics enter the market. An FDA study demonstrated that with even one generic competitor , the average manufacturer's price is reduced by up to 39%. Entry of four generics improves competition so much that prices are 79% less than the brand drug price before generic entry.

High prices of drugs hampers patients ability to afford their co-pays and deductibles for the medication they need. And these high prices are threatening long-term sustainability of our health insurance systems, both in the private market and in state and federal programs.

Unfortunately we have seen longer and longer waits for a life-saving drug to come off patent. One reason is the over-patenting of pharmaceutical products to extend the monopoly pricing of a patented drug, with only minor tweaks and changes in the medication as justifications for new patents. And with that over-patenting, we know that there are some patents that were wrongly

granted.Today the PTO is dealing with thousands of patent applications and even one drug might have dozens of applications before the PTO. We would hope the patent examiners always get it right, but there are bound to be mistakes.

Academic research shows that between 27% and 40% of granted patents are found invalid when challenged, suggesting that an estimated 100,000 invalid patents are erroneously granted annually.

So it is important to ensure that we have strong systems in place to challenge wrongly-granted patents. The PTAB is a less expensive and faster way to challenge improper patents and importantly allows "anyone" to bring evidence before a panel of experts at the Patent and Trademarks office. PREVAIL would change all that. **Please see our attached fact sheet for a more detailed explanation of why PREVAIL will undermine one important way to bring generics to market sooner and allow a competitive market to work to bring down drug prices. Please vote NO on S. 2220 (PREVAIL).**

Please also vote NO on S 2140 (PERA). Changing what is eligible to be patented would significantly change America's patent system. Patent eligibility is only one requirement of being awarded a patent. But it is the one that ensures patents are granted to only those things that are truly inventions. The changes proposed in PERA open the door to patent compounds that exist in nature which nobody invented, but are newly discovered. This dramatic change could have devastating effects on drug pricing by expanding the universe of items that can have a patent, meaning it will be easier than ever for drug companies to build patent thickets which keep competitors off the market.

We urge you to consider the broader ramifications of these bills on patients and prescription drug prices as a whole. We are happy to meet to discuss our concerns and address your questions. Thank you for your time.

Sincerely,

Patricia Kelmar
Senior Director, Health Care Campaigns

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