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Eliminating Thickets to Improve Competition (ETHIC) Act

Led in the Senate by: Senators Peter Welch (D-Vt.); Josh Hawley (R-Mo.); Amy Klobuchar (D-Minn.)

Introduced in the House by: Representative Jodey Arrington (D-TX-19)

Background:

Americans pay more for prescription medications than their counterparts in other comparable countries. Pharmaceutical companies game the patent system —which is designed to protect true innovation—by building anticompetitive "patent thickets" at a high cost to the American people. This bill will limit Big Pharma's ability to exploit the U.S. court and patent system to prevent generic competitors from entering the market. This bill benefits patients while rewarding true innovation and enhancing fair market competition.

Why Patent Thicket Reform is Necessary:

A "patent thicket" describes a web of patents filed on a single existing product to create barriers to competition and extend effective patent life. The US Patent and Trademark office (USPTO) grants patents on new and novel inventions, for example the active ingredient of lifesaving drug – this is known as the "parent patent."

Pharma companies build patent thickets by making small changes to a parent patent and subsequently applying for "off-spring patents." USPTO may reject some off-spring patent applications because they have been deemed not different enough or not "patentably distinct" from the parent patent.

To circumvent a rejection of a such a patent application, Pharma companies file terminal disclaimers on these off-spring patents applications. Terminally disclaimed patents have the same patent protection period as the parent patent but allows Pharma companies to build a thicket around the parent patent.

Challenging the validity of an off-spring patent is costly and time consuming, because a generic or biosimilar that seeks to challenge the validity of an off-spring patent must invalidate every single patent in a thicket.

For example, AbbVie built a patent thicket of over 130 additional and duplicative off-spring patents on the drug Humira. AbbVie applied for numerous offspring patents, including on the injector device used to deliver the medication, the injector firing button, and a specific dosage of Humira for a condition that it was already known to treat. AbbVie has stated that any generic or biosimilar company seeking to challenge any patents in their thicket would have a total litigation time of 4 to 5 years.

An investigation in 2021 found that U.S. companies filed more than 600 patents on just 12 drugs, with the potential for an aggregate total of 290 additional years of market monopoly, driving up the price of medications and cost to patients.

A recent study looking at biologic drug patents filed from 2000 to 2015 found a 200% increase in patents filed by companies that made minor substantive changes to their drugs. Patent thickets do nothing to encourage innovation, research, and development of new pharmaceuticals.

Legislation:

The *ETHIC Act* streamlines patent litigation by limiting the number of patents per patent thicket a pharmaceutical company can assert to **one**, reducing the burden on generic and biosimilar companies. **Patent holders who have created a thicket would only be allowed to assert one patent per thicket in litigation.** They may choose which patent from each thicket to assert to protect their invention.

This proposal safeguards quality patents that improve existing drugs, benefiting patients, while lowering the litigation barrier for generics and biosimilars to enter the market. The bill prohibits a patent owner from asserting multiple patents from the same thicket in separate actions against the same alleged infringer to circumvent the intent of the law.

This proposal is a modest, commonsense reform that codifies the practice of many federal district courts across the country. District courts already frequently impose a limit on the number of patents or patent claims the holder can assert in litigation for simplicity, time, and cost.