S. 2780, the Medication Affordability and Patent Integrity Act

Sponsored by Senators Hassan (D-NH) and Braun (R-IN)

A bill to close a loophole that limits patients' access to low-cost medications.

Background: When marketing a new medication, drug manufacturers follow two separate approval processes. First, drug manufacturers seek market approval from the FDA by submitting a new drug application. Second, drug manufacturers seek a primary patent on their product by submitting a patent application to the Patent Office.

The Problem: Although FDA and the Patent Office are supposed to receive similar basic information from drug manufacturers about the use of the new drug, its formulation, and other technical characteristics, the agencies have limited authority to coordinate and share this basic drug information – and confirm they are receiving the same information.

Drug manufacturers have used this loophole to keep drug prices high by providing different or incomplete information when applying for patents, allowing them to unfairly extend patent protections and effectively denying patients access to low-cost versions of their medications.

Specifically, drug manufacturers using this scheme provide FDA with the full product details needed to secure a drug's approval – while at the same time omitting key, basic information from the initial product patent with Patent Office. When drugmakers omit basic information from their initial patent, they can patent those original characteristics of the drug years later – artificially generating additional years of market exclusivity that allows them to block low-cost alternatives of the same drug from entering the market.

For example, biologic drugmakers receive 12 years of market exclusivity for new medications. When this time period is about to expire, companies can use the FDA-Patent Office loophole to patent technical aspects of the drug that were known to FDA years earlier at the time of the drug's approval, but that were not previously disclosed to the Patent Office.

The Solution: S. 2780, introduced by Senators Hassan and Braun, would require brand name drugmakers to attest that any information submitted to FDA relating to patentability is consistent with their submission to the Patent Office. The bill does not require that all information submitted to FDA also go to Patent Office. Rather, the bill requires manufacturers to attest that they are not *knowingly* submitting conflicting information across the two agencies at the time of their submissions. **CBO estimates that this bill would save $100 million over 10 years.**

The bill would require that:

1. Manufacturers attest that they have not *knowingly* made inconsistent statements to either FDA or the Patent Office for purposes of seeking marketing approval or patent protection;

2. Manufacturers submit to the Patent Office any information that was submitted to FDA that is directly relevant to the patentability of their product, when appropriate; and

3. Failure to comply with the attestation or information disclosure requirement could render a patent unenforceable if the patentee is found to have acted improperly in later litigation.

This bill is endorsed by the AARP, ERISA Industry Committee, Patients for Affordable Drug Prices Now, Campaign for Sustainable Rx Pricing, the National Multiple Sclerosis Society, Generation Patient, Allergy & Asthma Network, Alliance for Community Health Plans, American Society of Health-System Pharmacists, Asthma and Allergy Foundation of America, Bonnell Foundation, Boomer Esiason Foundation, CanDo Multiple Sclerosis, Cystic Fibrosis Research Institute, Emily's Entourage, HealthyWomen, Lupus and Allied Diseases Association, Inc. MS Views & News, Multiple Sclerosis Association of America, Multiple Sclerosis Foundation, Patients Rising, Rock CF Foundation

CASE STUDY: EYLEA

The medication Eylea was approved in 2011 to treat macular degeneration, a common eye disorder among older adults. Eylea is used by over 300,000 older adults, and in 2021 each patient on Medicare who needed Eylea spent an average of $2,000 on the drug. Medicare spent over $3 billion total on this drug in 2021.

The primary patent for Eylea expired in June 2023, and low-cost biosimilars of Eylea were in development and poised to enter the market at a much lower price.

Unfortunately, a secondary product patent – filed a decade after the primary product patent – could extend the blockbuster drug's market exclusivity until the year 2040.

The secondary product patent was filed on a feature of the drug (oxidation profile) that was known to the manufacturer years earlier and disclosed to the FDA in 2011 during marketing approval.

S. 2780 would close this loophole, which blocks low-cost alternatives from approval.