Reforming America's Patent Laws: Boosting Competition Can Lower Prescription Drug Costs for Employers and Employees

As drug costs continue to rise, employers are constantly searching for ways to bring affordable drugs more quickly to workers and their families. **Biosimilars can provide much-needed affordability, but only if they are accessible to consumers.** Acting to reform America's broken patent system is critical to striking the balance between innovation and competition so Americans have more timely access to more affordable drug therapies.

- More than 155 million Americans receive health care benefits through their employer, with large employers paying more than 80 percent of health care costs on behalf of their employees.
- Prescription drugs have been the fastest-growing component of health benefit cost for years, but in 2023 pharmacy benefit costs jumped 8.4%, following an increase of 6.4% in 2022.
- Despite rising health plan costs, large employers largely avoided shifting additional costs to employees through higher deductibles, copays, or out-of-pocket maximums in 2023. For example, among large employers, the average in-network PPO deductible rose by just $2 in 2023.
- According to some reports, prices for the 12 best-selling drugs in the United States increased by close to 150 percent between 2012 and 2018.
- Together, generic and biosimilar drugs represent a whopping 90 percent of all U.S. prescriptions, but only 13 percent of overall drug spending.

By the Numbers: Generic and Biosimilar Medicines Provide Significant Relief for Patients Living with Chronic and Acute Conditions

Savings by Condition	
Condition	**Total Savings (Primary Condition + Comorbidities)**
Heart Disease	$118.1 billion
Mental Illness	$76.4 billion
Diabetes	$61 billion
Cancers	$25.5 billion
Allergies & Asthma	$13 billion
Arthritis	$5.6 billion
Multiple Sclerosis	$4.6 billion
Crohn's & Colitis	$2.4 billion
Bone Disease (Osteoporosis, Osteoarthritis, etc.)	$2.2 billion
Autoimmune Diseases	$350 million

Source: Association of Accessible Medicine: The U.S. Generic & Biosimilar Medicines Savings Report

- In 2020, ERIC launched a groundbreaking initiative to better understand the role that biosimilars could play in reducing health care costs, and found that biosimilars saved employers, employees, and their families significant amounts of money.

ERIC at Work: Meaningful Progress Toward More Affordable Prescription Drugs

ERIC strongly supported H.R. 1520 (the *Purple Book Continuity Act*) and H.R. 1503 (the *Orange Book Transparency Act*). **These bills, signed into law in 2020 and 2021, codify, clarify, and improve FDA responsibilities to publish information that helps generic companies better understand the current exclusivity landscape and empowers generic companies to navigate the requirements to get generics to market more efficiently.**

Reforming America's Patent Laws: Leveraging Legislation and Regulation to Boost Competition and Cut Costs

THE PROBLEM

Over the past two decades, drug manufacturers have abused the patent system to extend monopolies for biologics and certain brand-name prescription drugs far beyond the 12-year (for biologics) and 20-year (for brand-name drugs) exclusivity period as permitted under the law. Drug manufacturers do this primarily by engaging in the following practices:

- **Secondary-Structure Patents** – A common strategy to maintain market exclusivity is to patent the same drug using two distinct patent filings. First, through a "*primary-structure filing*" (which is essentially the initial patent claim), followed up by a "*secondary-structure filing*" (which inappropriately prolongs market exclusivity for the same drug).
- **Obviousness-Type Double Patenting** – Similar to the practice of using secondary-structure patents to extend the exclusivity of a patent, drug manufacturers engage in a practice called "obviousness-type double patenting" (OTDP). Here, drug manufacturers submit patent requests multiple times on virtually the same drug, effectively creating what industry-experts call "*patent thickets.*"
- ***Terminal Disclaimers*** – Importantly, the United States is the only country that allows OTDP through the use of what experts call "*terminal disclaimers*," where drug manufacturers are able to claim multiple patents on the same drug. This leads to large, duplicative patent thickets that make it exceedingly difficult to invalidate a particular patent because multiple patents are tied together through these terminal disclaimers.

The long-tail in exclusivity enabled by these practices prevents generic and biosimilar drugs from coming to market to compete with the patented prescription drugs. The lack of competition keeps the cost of prescription drugs high and also frustrates the underlying purpose of the *Biologics Price Competition and Innovation and Hatch Waxman Acts.*

THE SOLUTION

Congress must pass legislation to prohibit the above stated practices, along with prohibiting other anti-competitive practices that are used to manipulate the market. Specifically, the House and Senate must pass a number of bipartisan bills that have already been marked up and passed by the House and/or Senate Judiciary Committees, including:

- S. 79 and H.R. 1717 (the *Interagency Patent Coordination and Improvement Act);* S. 113 *(the Prescription Pricing for the People Act of 2023*); S. 142 (the *Preserve Access to Affordable Generics and Biosimilars Act*); S. 148 (the *Stop STALLING Act*); S. 150 (the *Affordable Prescriptions for Patients Act*); and other bipartisan, bicameral bills including S. 2780 and H.R. 5429 (the *Medication Affordability and Patent Integrity Act*) and S. 3583 and H.R. 6986 (*A Bill to Address Patent Thickets*).

The United States Patent and Trademark Office (USPTO) must be able to:

- Coordinate with the Food and Drug Administration (FDA) to, among other things, source back to the primary-structure filing to secondary-structure filings and communicate with the FDA to seek disclosures and information relating to a secondary-structure filing.
- Engage directly with FDA officials to ask questions about the technical details of a particular patent filing, obtain relevant information from the drug regulatory dossier, and request that FDA officials conduct additional research on a particular brand-name drug.