The "Patent Thicket" Talking Point Falls Apart Under Scrutiny

America's intellectual property (IP) system helps deliver new innovative medicines while also ensuring robust generic competition. Today, nearly 90% of prescriptions are filled with low-cost generics and biosimilars, saving patients and the health care system trillions of dollars over the past decade.

Critics of the U.S. IP system claim that drug companies obtain excessive amounts of patents to lock out lower cost generic competitors. But those claims fail to show a link between patent counts and the timing of generic entry. These misleading attacks threaten to undermine the very system that fuels American leadership in biopharmaceutical innovation while also paving the way for low-cost generic competition.

The facts

Nearly 90%

of U.S. prescriptions are filled with generics and biosimilars.

$3.4T

saved by generics and biosimilars over the past decade.

13-14 years

average time before generic competition enters the market.

18% lower

average prescription prices in Medicare and Medicaid due to higher generic utilization in the U.S. compared to other OECD countries.

Five things to know

1. **Medicines are highly complex products that often incorporate multiple inventions** that can include the active ingredient, formulation, dosage form, use in a particular disease or manufacturing methods. Each of these can represent an innovation that meets patentability standards, and none of them can extend the life of prior patents.

2. **The patent system enables drug companies to make enormous investments and take huge risks on drug development.** While they patent less, they invest more than other sectors. Among sectors that rely on patents, the biopharmaceutical sector ranks in the middle of the pack on total patents but invests more R&D per patent – over $12 million – than any other sector. But even with that investment, sales per patent are also squarely in the middle of all industries, reflecting the high costs and risks associated with drug development.

3. **More patents do not necessarily mean longer time to generic entry.** A 2024 USPTO study found no correlation between the number of patents on a product and the length of actual market exclusivity until generic entry.

4. 81%

   Generic companies regularly challenge patents reflecting a system working as intended. Just 9% of brand drugs had a generic manufacturer challenge patents via Hatch Waxman litigation in 1995. But by 2019, 81% of drugs had such challenges. Additionally, courts routinely manage these cases to focus only on the patents that matter most, further reducing litigation hurdles.

5. **Prescription drugs are a small/stable share of overall health care spending.** Prescription medicines account for just 14% of overall U.S. health care spending, the same share as in the past decade – even as new medicines have reached patients.

The bottom line:

America's intellectual property system supports innovation, competition and lower costs. It helps researchers develop new innovative medicines while ensuring patients benefit from low-cost generic competition.