

S 1435

Affordable Prescriptions for Patients Act of 2021

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Commerce

Introduced: Apr 28, 2021

Current Status: Committee on the Judiciary. Ordered to be reported with an amendment in the nature of a substitute if

Latest Action: Committee on the Judiciary. Ordered to be reported with an amendment in the nature of a substitute favorably. (Jul 29, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/1435>

Sponsor

Name: Sen. Cornyn, John [R-TX]

Party: Republican • **State:** TX • **Chamber:** Senate

Cosponsors (16 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Blumenthal, Richard [D-CT]	D · CT		Apr 28, 2021
Sen. Grassley, Chuck [R-IA]	R · IA		Jul 15, 2021
Sen. Durbin, Richard J. [D-IL]	D · IL		Jul 28, 2021
Sen. Klobuchar, Amy [D-MN]	D · MN		Jul 28, 2021
Sen. Murray, Patty [D-WA]	D · WA		Aug 2, 2021
Sen. Booker, Cory A. [D-NJ]	D · NJ		Aug 3, 2021
Sen. Cruz, Ted [R-TX]	R · TX		Aug 3, 2021
Sen. Hawley, Josh [R-MO]	R · MO		Aug 3, 2021
Sen. Ossoff, Jon [D-GA]	D · GA		Aug 3, 2021
Sen. Ernst, Joni [R-IA]	R · IA		Sep 20, 2021
Sen. King, Angus S., Jr. [I-ME]	I · ME		Sep 21, 2021
Sen. Leahy, Patrick J. [D-VT]	D · VT		Sep 21, 2021
Sen. Peters, Gary C. [D-MI]	D · MI		Sep 21, 2021
Sen. Smith, Tina [D-MN]	D · MN		Sep 21, 2021
Sen. Braun, Mike [R-IN]	R · IN		Sep 30, 2021
Sen. Kelly, Mark [D-AZ]	D · AZ		Mar 15, 2022

Committee Activity

Committee	Chamber	Activity	Date
Judiciary Committee	Senate	Markup By	Jul 29, 2021

Subjects & Policy Tags

Policy Area:

Commerce

Related Bills

Bill	Relationship	Last Action
117 HR 5237	Related bill	Nov 1, 2022: Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.
117 HR 5260	Related bill	Nov 1, 2022: Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.
117 HR 2884	Related bill	Sep 30, 2021: Ordered to be Reported in the Nature of a Substitute by Voice Vote.
117 HR 2873	Related bill	Sep 29, 2021: Ordered to be Reported in the Nature of a Substitute by the Yeas and Nays: 27 - 16.

Summary (as of Apr 28, 2021)

Affordable Prescriptions for Patients Act of 2021

This bill prohibits product hopping by drug manufacturers, authorizes the Federal Trade Commission to enforce this prohibition, and imposes limits on patent litigation involving biological products.

Generally, *product-hopping* describes a situation where, when the patents on a reference drug (or biological product) expire, the manufacturer switches to a follow-on product that is covered by a later-expiring patent. Under this bill, a *follow-on product* is a modified version of the reference drug that shares an indication (what the drug is used for) with the reference drug.

The bill presumes product hopping has occurred when a reference drug manufacturer, after receiving notice that the Food and Drug Administration (FDA) has received an application to market a competing generic (or biosimilar) version, takes certain actions such as withdrawing the reference drug from the market and selling a follow-on product.

A drug manufacturer may rebut these presumptions by demonstrating that its conduct was not intended to limit competition.

The bill also limits in certain instances the number of patents that a reference biological product manufacturer can assert in a patent infringement lawsuit against a company seeking to sell a biosimilar version. Specifically, if the biosimilar manufacturer completes certain actions as part of an abbreviated pathway to get FDA market approval, the bill limits, subject to exceptions and waivers, the number of certain types of patents that the reference product manufacturer may assert, such as patents filed more than four years after the reference product received market approval.

Actions Timeline

- **Jul 29, 2021:** Committee on the Judiciary. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Apr 28, 2021:** Introduced in Senate
- **Apr 28, 2021:** Read twice and referred to the Committee on the Judiciary.