

HR 3991

Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019

Congress: 116 (2019–2021, Ended)

Chamber: House

Policy Area: Commerce

Introduced: Jul 25, 2019

Current Status: Ordered to be Reported (Amended).

Latest Action: Ordered to be Reported (Amended). (Nov 21, 2019)

Official Text: <https://www.congress.gov/bill/116th-congress/house-bill/3991>

Sponsor

Name: Rep. Johnson, Henry C. "Hank," Jr. [D-GA-4]

Party: Democratic • **State:** GA • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Roby, Martha [R-AL-2]	R · AL		Jul 25, 2019

Committee Activity

Committee	Chamber	Activity	Date
Judiciary Committee	House	Discharged from	Nov 19, 2019

Subjects & Policy Tags

Policy Area:

Commerce

Related Bills

Bill	Relationship	Last Action
116 HR 2486	Related bill	Jul 23, 2020: Message on House action received in Senate and at desk: House amendments to Senate amendment.
116 S 1416	Related bill	Jun 28, 2019: Placed on Senate Legislative Calendar under General Orders. Calendar No. 132.

Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019

This bill limits in certain instances the number of patents that the manufacturer of a biologic drug can assert in a lawsuit against a company seeking to sell a biosimilar version of that drug. (A biologic drug is produced through natural processes or isolated from natural sources. A biosimilar version is substantially similar to the original biologic, which is the reference product, and is often marketed as a less expensive alternative.)

The bill's provisions apply to an existing framework that gives the biosimilar manufacturer an abbreviated path to Food and Drug Administration approval to sell the biosimilar. Specifically, if the biosimilar manufacturer completes certain actions under the framework, such as sharing certain information about its product with the reference product manufacturer, the bill limits the number of certain patents that the reference product manufacturer may assert in a lawsuit, such as patents that were filed more than four years after the reference product received market approval. The limit shall not apply to patents claiming certain methods for using the biologic drug.

The court in which the infringement lawsuit is filed may increase the limit if justice so requires or if there is good cause for the increase.

Actions Timeline

- **Nov 21, 2019:** Committee Consideration and Mark-up Session Held.
- **Nov 21, 2019:** Ordered to be Reported (Amended).
- **Nov 19, 2019:** Subcommittee on Courts, Intellectual Property, and the Internet Discharged.
- **Aug 28, 2019:** Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.
- **Jul 25, 2019:** Introduced in House
- **Jul 25, 2019:** Referred to the House Committee on the Judiciary.