S 214

Preserve Access to Affordable Generics Act

Congress: 113 (2013–2015, Ended)
Chamber: Senate
Policy Area: Commerce
Introduced: Feb 4, 2013
Current Status: Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearin
Latest Action: Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearings held. (Jul 23, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/senate-bill/214

Sponsor

Name: Sen. Klobuchar, Amy [D-MN]
Party: Democratic • **State:** MN • **Chamber:** Senate

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Durbin, Richard J. [D-IL]	D · IL		Feb 4, 2013
Sen. Franken, Al [D-MN]	D · MN		Feb 4, 2013
Sen. Grassley, Chuck [R-IA]	R · IA		Feb 4, 2013
Sen. Johnson, Tim [D-SD]	D · SD		Feb 4, 2013
Sen. Sanders, Bernard [I-VT]	I · VT		Mar 14, 2013
Sen. Boxer, Barbara [D-CA]	D · CA		May 14, 2013
Sen. Whitehouse, Sheldon [D-RI]	D · RI		Jan 16, 2014

Committee Activity

Committee	Chamber	Activity	Date
Judiciary Committee	Senate	Hearings By (subcommittee)	Jul 23, 2013

Subjects & Policy Tags

Policy Area:

Commerce

Related Bills

No related bills are listed.

Summary (as of Feb 4, 2013)

Preserve Access to Affordable Generics Act - Amends the Federal Trade Commission Act to authorize the Federal Trade Commission (FTC) to initiate a proceeding against parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug. Establishes a presumption that any such agreement has anticompetitive effects and is unlawful if the filer of an abbreviated new drug (generic) application receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug for any period of time. Allows an exception to such presumption if the parties to the agreement demonstrate by clear and convincing evidence, based on specified competitive factors, that the pro-competitive benefits of the agreement outweigh the anticompetitive effects.

Exempts from the restrictions of this Act a resolution or settlement of a patent infringement claim if the only consideration granted by the brand name manufacturer to the generic manufacturer is: (1) the right to market the generic drug in the United States prior to the expiration of any patent that is the basis for the patent infringement claim or any patent right or other statutory exclusivity that would prevent the marketing of such drug, (2) a payment for reasonable litigation expenses not exceeding $7.5 million, and (3) a covenant not to sue on any claim that the generic drug infringes a U.S. patent.

Allows review of FTC enforcement orders under this Act in federal court. Imposes civil penalties for violations of this Act.

Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to require a brand name manufacturer and generic manufacturer to submit to the FTC any other agreements the parties enter into within 30 days of entering into an agreement related to the manufacturing, marketing, or sale of the brand name or generic drug or the exclusivity period. Requires the Chief Executive Officer or the company official responsible for negotiating any such agreement to file a certification that materials filed with respect to such agreement are complete, final, and exclusive.

Amends the Federal Food, Drug, and Cosmetic Act to forfeit the 180-day exclusivity period for the marketing of a generic drug if there is a final decision of the FTC or a court that an agreement has violated this Act.

Grants the FTC exclusive authority to litigate matters relating to anticompetitive practices in connection with the sale of generic brand drugs. Establishes a three-year limitation period for bringing FTC enforcement actions (other than cease and desist requests) under this Act.

Actions Timeline

- **Jul 23, 2013:** Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearings held.
- **Feb 4, 2013:** Introduced in Senate
- **Feb 4, 2013:** Read twice and referred to the Committee on the Judiciary.