To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 4, 2013

Ms. Klobuchar (for herself, Mr. Grassley, Mr. Durbin, Mr. Franken, and Mr. Johnson of South Dakota) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

SECTION 1. SHORT TITLE.

This Act may be cited as the “Preserve Access to Affordable Generics Act”.

SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) In 1984, the Drug Price Competition and Patent Term Restoration Act (Public Law 98–417) (referred to in this Act as the “1984 Act”), was en-
acted with the intent of facilitating the early entry
of generic drugs while preserving incentives for inno-

(2) Prescription drugs make up 10 percent of
the national health care spending but for the past
decade have been one of the fastest growing seg-
ments of health care expenditures.

(3) Until recently, the 1984 Act was successful
in facilitating generic competition to the benefit of
consumers and health care payers—although 67 per-
cent of all prescriptions dispensed in the United
States are generic drugs, they account for only 20
percent of all expenditures.

(4) Generic drugs cost substantially less than
brand name drugs, with discounts off the brand
price sometimes exceeding 90 percent.

(5) Federal dollars currently account for an es-
timated 35 percent of the $263,000,000,000 spent
on prescription drugs, and this share is expected to
rise to 42 percent by 2021.

(6)(A) In recent years, the intent of the 1984
Act has been subverted by certain settlement agree-
ments between brand companies and their potential
generic competitors that make “reverse payments”
which are payments by the brand company to the
generic company.

(B) These settlement agreements have unduly
delayed the marketing of low-cost generic drugs con-
trary to free competition, the interests of consumers,
and the principles underlying antitrust law.

(C) Because of the price disparity between
brand name and generic drugs, such agreements are
more profitable for both the brand and generic man-
ufacturers than competition, and will become in-
creasingly common unless prohibited.

(D) These agreements result in consumers los-
ing the benefits that the 1984 Act was intended to
provide.

(b) PURPOSES.—The purposes of this Act are—

(1) to enhance competition in the pharma-
ceutical market by stopping anticompetitive agree-
ments between brand name and generic drug manu-
facturers that limit, delay, or otherwise prevent com-
petition from generic drugs; and

(2) to support the purpose and intent of anti-
trust law by prohibiting anticompetitive practices in
the pharmaceutical industry that harm consumers.
SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.


(1) redesignating section 28 as section 29; and

(2) inserting before section 29, as redesignated, the following:

"SEC. 28. PRESERVING ACCESS TO AFFORDABLE GENERICS.

“(a) IN GENERAL.—

“(1) ENFORCEMENT PROCEEDING.—The Federal Trade Commission may initiate a proceeding to enforce the provisions of this section against the 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 product.

“(2) PRESUMPTION.—

“(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and be unlawful if—

“(i) an ANDA filer receives anything of value; and

“(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time."
“(B) EXCEPTION.—The presumption in subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anti-competitive effects of the agreement.

“(b) COMPETITIVE FACTORS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall consider—

“(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;

“(2) the value to consumers of the competition from the ANDA product allowed under the agreement;

“(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;

“(4) the revenue the ANDA filer would have received by winning the patent litigation;

“(5) the reduction in the NDA holder’s revenues if it had lost the patent litigation;

“(6) the time period between the date of the agreement conveying value to the ANDA filer and
the date of the settlement of the patent infringement claim; and

“(7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

“(c) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

“(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

“(2) that the agreement’s provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is pro-competitive, although such evidence may be relevant to the fact finder’s determination under this section.

“(d) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part of the resolution or settlement includes only one or more of the following:

“(1) The right to market the ANDA product in the United States prior to the expiration of—
“(A) any patent that is the basis for the patent infringement claim; or

“(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

“(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

“(3) A covenant not to sue on any claim that the ANDA product infringes a United States patent.

“(e) REGULATIONS AND ENFORCEMENT.—

“(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 553 of title 5, United States Code, regulations implementing and interpreting this section. These regulations may exempt certain types of agreements described in subsection (a) if the Commission determines such agreements will further market competition and benefit consumers. Judicial review of any such regulation shall be in the United States District Court for the District of Columbia pursuant to section 706 of title 5, United States Code.

“(2) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

“(3) JUDICIAL REVIEW.—Any person, partnership or corporation that is subject to a final order
of the Commission, issued in an administrative adju-
dicative proceeding under the authority of subsection
(a)(1), may, within 30 days of the issuance of such
order, petition for review of such order in the United
States Court of Appeals for the District of Columbia
Circuit or the United States Court of Appeals for
the circuit in which the ultimate parent entity, as
defined at 16 CFR 801.1(a)(3), of the NDA holder
is incorporated as of the date that the NDA is filed
with the Secretary of the Food and Drug Adminis-
tration, or the United States Court of Appeals for
the circuit in which the ultimate parent entity of the
ANDA filer is incorporated as of the date that the
ANDA is filed with the Secretary of the Food and
Drug Administration. In such a review proceeding,
the findings of the Commission as to the facts, if
supported by evidence, shall be conclusive.
“(f) ANTITRUST LAWS.—Nothing in this section shall
be construed to modify, impair or supersede the applica-
bility of the antitrust laws as defined in subsection (a)
of the 1st section of the Clayton Act (15 U.S.C. 12(a))
and of section 5 of this Act to the extent that section 5
applies to unfair methods of competition. Nothing in this
section shall modify, impair, limit or supersede the right
of an ANDA filer to assert claims or counterclaims against
any person, under the antitrust laws or other laws relating
to unfair competition.

“(g) Penalties.—

“(1) Forfeiture.—Each person, partnership
or corporation that violates or assists in the violation
of this section shall forfeit and pay to the United
States a civil penalty sufficient to deter violations of
this section, but in no event greater than 3 times the
value received by the party that is reasonably attrib-
utable to a violation of this section. If no such value
has been received by the NDA holder, the penalty to
the NDA holder shall be sufficient to deter viola-
tions, but in no event greater than 3 times the value
given to the ANDA filer reasonably attributable to
the violation of this section. Such penalty shall ac-
crue to the United States and may be recovered in
a civil action brought by the Federal Trade Commiss-
ion, in its own name by any of its attorneys des-
ignated by it for such purpose, in a district court of
the United States against any person, partnership or
corporation that violates this section. In such ac-
tions, the United States district courts are empow-
ered to grant mandatory injunctions and such other
and further equitable relief as they deem appro-
priate.
“(2) CEASE AND DESIST.—

“(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a person, partnership or corporation in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such person, partnership or corporation at any time before the expiration of one year after such order becomes final pursuant to section 5(g).

“(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to such person’s, partnership’s or corporation’s violation of this section shall be conclusive unless—

“(i) the terms of such cease and desist order expressly provide that the Commission’s findings shall not be conclusive; or

“(ii) the order became final by reason of section 5(g)(1), in which case such find-
ing shall be conclusive if supported by evi-
dence.

“(3) CIVIL PENALTY.—In determining the
amount of the civil penalty described in this section,
the court shall take into account—

“(A) the nature, circumstances, extent,
and gravity of the violation;

“(B) with respect to the violator, the de-
gree of culpability, any history of violations, the
ability to pay, any effect on the ability to con-
tinue doing business, profits earned by the
NDA holder, compensation received by the
ANDA filer, and the amount of commerce af-
feeted; and

“(C) other matters that justice requires.

“(4) REMEDIES IN ADDITION.—Remedies pro-
vided in this subsection are in addition to, and not
in lieu of, any other remedy provided by Federal
law. Nothing in this paragraph shall be construed to
affect any authority of the Commission under any
other provision of law.

“(h) DEFINITIONS.—In this section:

“(1) AGREEMENT.—The term ‘agreement’
means anything that would constitute an agreement
under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

“(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term ‘agreement resolving or settling a patent infringement claim’ includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

“(3) ANDA.—The term ‘ANDA’ means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

“(4) ANDA FILER.—The term ‘ANDA filer’ means a party who has filed an ANDA with the Food and Drug Administration.

“(5) ANDA PRODUCT.—The term ‘ANDA product’ means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

“(6) DRUG PRODUCT.—The term ‘drug product’ means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance,
generally, but not necessarily, in association with 1 or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

“(7) NDA.—The term ‘NDA’ means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

“(8) NDA HOLDER.—The term ‘NDA holder’ means—

“(A) the party that received FDA approval to market a drug product pursuant to an NDA;

“(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the ‘FDA Orange Book’) in connection with the NDA; or

“(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.
“(9) PATENT INFRINGEMENT.—The term ‘patent infringement’ means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

“(10) PATENT INFRINGEMENT CLAIM.—The term ‘patent infringement claim’ means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.

“(11) STATUTORY EXCLUSIVITY.—The term ‘statutory exclusivity’ means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(e)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act.”.

SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by—
(1) striking “the Commission the” and inserting the following: “the Commission—

“(1) the”;

(2) striking the period and inserting “; and”;

and

(3) inserting at the end the following:

“(2) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).”.

(b) Certification of Agreements.—Section 1112 of such Act is amended by adding at the end the following:

“(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: ‘I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a
contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.’.’.

SEC. 5. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.


SEC. 6. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking “or” after the semicolon;

(2) in subparagraph (E), by inserting “or” after the semicolon; and

(3) inserting after subparagraph (E) the following:

“(F) under section 28;”.

SEC. 7. STATUTE OF LIMITATIONS.

The Commission shall commence any enforcement proceeding described in section 28 of the Federal Trade
Commission Act, as added by section 3, except for an action described in section 28(g)(2) of the Federal Trade Commission Act, not later than 3 years after the date on which the parties to the agreement file the Notice of Agreement as provided by sections 1112(c)(2) and (d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

SEC. 8. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such Act or amendments to any person or circumstance shall not be affected thereby.