

STATE OF NEW YORK

488--A

Cal. No. 204

2025-2026 Regular Sessions

IN SENATE

(Prefiled)

January 8, 2025

Introduced by Sens. FERNANDEZ, ADDABBO, WEBB -- read twice and ordered printed, and when printed to be committed to the Committee on Consumer Protection -- reported favorably from said committee, ordered to first and second report, ordered to a third reading, passed by Senate and delivered to the Assembly, recalled, vote reconsidered, restored to third reading, amended and ordered reprinted, retaining its place in the order of third reading

AN ACT to amend the general business law, in relation to requiring prescription drug manufacturers to notify the attorney general of arrangements between pharmaceutical manufacturers resulting in the delay of the introduction of generic drugs

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. This act shall be known and may be cited as the "manufac-
2 turer disclosure and transparency act".

3 § 2. The general business law is amended by adding a new section 396-
4 rrr to read as follows:

5 § 396-rrr. Delay of introduction of generic medications. 1. For
6 purposes of this section, the following terms shall have the following
7 meanings:

8 (a) "Agreement" means anything that would constitute an agreement
9 under state law.

10 (b) "Attorney general" means the office of the New York state attorney
11 general.

12 (c) "Patent settlement agreement" means any agreement that is entered
13 into within sixty days of the resolution or the settlement of patent
14 litigation, or any other agreement that is contingent upon, provides a
15 contingent condition for, or is otherwise related to the resolution or
16 settlement of patent litigation, including, without limitation:

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

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1 (i) any agreement required to be provided to the federal trade commis-
2 sion or the antitrust division of the United States department of
3 justice under the Medicare Prescription Drug, Improvement, and Modern-
4 ization Act of 2003, Pub. L. No. 108-173;

5 (ii) any agreement between a biosimilar or interchangeable product
6 applicant and a biological product deemed a reference product sponsor
7 under the Biologics Price Competition and Innovation Act of 2009, Pub.
8 L. No. 111-148, that resolves patent claims between the applicant and
9 sponsor; or

10 (iii) any agreement between parties to a patent settlement agreement
11 executed sixty days before or after final execution of the patent
12 settlement agreement and which either: (A) is intended to relate to the
13 patent settlement agreement, such as including activities or actions
14 contemplated under the patent settlement agreement; (B) references the
15 patent settlement agreement or any obligation arising out of the patent
16 settlement agreement, or is otherwise related to the patent settlement
17 agreement; or (C) identifies, references or refers to any drug or active
18 pharmaceutical ingredient that was the subject matter or referenced by
19 the litigation that resulted in the patent settlement agreement.

20 (d) "Biological product," "biosimilar," "interchangeable product," and
21 "reference product sponsor" shall have the same meanings as defined
22 under section three hundred fifty-one of the public health service act,
23 42 U.S.C. 262 et seq., for licensure of a biological product, including
24 as biosimilar to, or interchangeable with, a reference biological prod-
25 uct.

26 (e) "Drug" means a drug as defined by 21 U.S.C. 321(g), and approved
27 for sale in the United States pursuant to section five hundred five of
28 the federal food, drug and cosmetics Act, 21 U.S.C 355 et seq.

29 (f) "Patent infringement claim" shall mean a claim for patent
30 infringement made under 35 U.S.C. 271.

31 (g) "Pharmaceutical manufacturer" shall mean any entity that manufac-
32 tures, either itself or through other entities, such as by contract, or
33 seeks to manufacture either a drug or biological product.

34 2. (a) Any pharmaceutical manufacturer doing business in this state
35 that enters into a patent settlement agreement resolving or settling a
36 patent infringement claim with another pharmaceutical manufacturer which
37 in any way sets or otherwise affects the date of commercial launch of a
38 drug or biological product by or on behalf of either pharmaceutical
39 manufacturer, shall, no later than thirty days after entering into the
40 patent settlement agreement, send notice and the full text, along with
41 any attachments and exhibits, of the patent settlement agreement to the
42 attorney general.

43 (b) Within sixty days of receiving notice pursuant to paragraph (a) of
44 this subdivision, the attorney general shall post on its website such
45 notice in a format and manner developed by the attorney general that is
46 searchable by drug, cost, disease, and manufacturer both for the brand
47 and generic drug for public review. Such notices shall be considered
48 public records for the purposes of article six of the public officers
49 law.

50 3. Failure to submit the required notice to the attorney general with-
51 in thirty days after entering into a patent settlement agreement pursu-
52 ant to subdivision two of this section shall result in a fine of ten
53 thousand dollars per day for each day of noncompliance.

54 § 3. If any clause, sentence, paragraph, subdivision, section, or part
55 of this act shall be adjudged by any court of competent jurisdiction to
56 be invalid or unenforceable, such judgment shall not affect, impair, or

1 invalidate the remainder thereof, but shall be confined in its operation
2 to the clause, sentence, paragraph, subdivision, section or part thereof
3 directly involved in the controversy in which such judgment shall have
4 been rendered. It is hereby declared to be the intent of the legislature
5 that this act would have been enacted even if such invalid provisions
6 had not been included herein.
7 § 4. This act shall take effect on the one hundred eightieth day after
8 it shall have become a law.