STATE OF NEW YORK

2289--A

2025-2026 Regular Sessions

IN ASSEMBLY

January 16, 2025

Introduced by M. of A. GALLAGHER, STIRPE, FORREST, MAMDANI, STERN, GONZALEZ-ROJAS, SIMON, SHIMSKY, COLTON, REYES, SIMONE, RAGA, SHRESTHA, SEAWRIGHT, RAMOS, ROSENTHAL, DAVILA, CLARK, LUPARDO, K. BROWN, EPSTEIN, SANTABARBARA, ROMERO, KELLES, JACOBSON -- read once and referred to the Committee on Consumer Affairs and Protection -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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:

Section 1. This act shall be known and may be cited as the "manufacturer disclosure and transparency act".

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

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

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

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

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

(i) any agreement required to be provided to the federal trade commission or the antitrust division of the United States department of

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

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justice under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173;

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

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

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

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

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

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

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

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

3. Failure to submit the required notice to the attorney general within thirty days after entering into a patent settlement agreement pursuant to subdivision two of this section shall result in a fine of ten thousand dollars per day for each day of noncompliance.

§ 3. If any clause, sentence, paragraph, subdivision, section, or part of this act shall be adjudged by any court of competent jurisdiction to be invalid or unenforceable, such judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section or part thereof

directly involved in the controversy in which such judgment shall have been rendered. It is hereby declared to be the intent of the legislature that this act would have been enacted even if such invalid provisions had not been included herein.

§ 4. This act shall take effect on the one hundred eightieth day after it shall have become a law.