AMENDED IN SENATE JULY 11, 2019

AMENDED IN SENATE JUNE 17, 2019

AMENDED IN ASSEMBLY MAY 16, 2019

AMENDED IN ASSEMBLY APRIL 10, 2019

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 824

Introduced by Assembly Member Wood
(Coauthor: Assembly Member Melendez)

February 20, 2019

An act to add Division 114.01 (commencing with Section 134000) to the Health and Safety Code, relating to business.

LEGISLATIVE COUNSEL'S DIGEST

AB 824, as amended, Wood. Business: preserving access to affordable drugs.

The Cartwright Act makes every trust, subject to specified exemptions, unlawful, against public policy, and void and defines "trust" for purposes of the act as a combination of capital, skill, or acts by 2 or more persons, defined as corporations, firms, partnerships, and associations, for certain designated purposes. Under existing law, these purposes include creating or carrying out restrictions in trade or commerce or preventing competition in manufacturing, marketing, transportation, sale, or purchase of merchandise, produce, or any commodity. The Unfair Practices Act makes certain business practices unlawful, including unfair competition. Under existing law, unfair competition is defined to include an unlawful, unfair, or fraudulent business act or practice,

unfair, deceptive, untrue, or misleading advertising, and any false representations to the public.

This bill would provide that an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, is to be presumed to have anticompetitive effects if a nonreference drug filer receives anything of ~~value~~ *value, as defined,* from another company asserting patent infringement and if the nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time, as specified. The bill would provide various exceptions to this prohibition, including, among others, if the agreement has directly generated procompetitive benefits that could not be achieved by less restrictive means and that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement. The bill would make a violation of these provisions punishable by a civil ~~penalty, as specified, and~~ *penalty that is recoverable only in a civil action brought by the Attorney General, as specified. The bill* would provide that a violator is liable for any other remedies available under the Cartwright Act, the Unfair Practices Act, or the unfair competition law. The bill would require a cause of action to enforce those provisions be commenced within 4 years after the course of action accrued. The bill would define various terms for these purposes.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 114.01 (commencing with Section 134000) is added to the Health and Safety Code, to read:

DIVISION 114.01. PRESERVING ACCESS TO AFFORDABLE DRUGS

134000. For purposes of this division:

(a) "ANDA" means abbreviated new drug application.

(b) "ANDA filer" means a party that owns or controls an ANDA filed with the Food and Drug Administration or has the exclusive rights under that ANDA to distribute the ANDA product.

(c) "Agreement" means anything that would constitute an agreement under California state law or a "trust" under the Cartwright Act (Chapter 2 (commencing with Section 16700) of Division 7 of the Business and Professions Code).

(d) "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. This shall include, but is not limited to, the following:

(1) Any agreement required to be provided to the Federal Trade Commission or the Antitrust Division of the United States Department of Justice under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173).

(2) Any agreement between a biosimilar or interchangeable product applicant and a reference product sponsor under the Biologics Price Competition and Innovation Act of 2009 (BPCIA) (Public Law 111-148) that resolves patent claims between the applicant and sponsor.

(e) "Biosimilar biological product application filer" means a party that owns or controls a biosimilar biological product application filed with the Food and Drug Administration under Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for licensure of a biological product as biosimilar to, or interchangeable with, a reference product, or that has the exclusive rights under the application to distribute the biosimilar biological product.

(f) "NDA" means new drug application.

(g) "Nonreference drug filer" means either:

(1) An ANDA filer.

(2) A biosimilar biological product application filer.

(h) "Nonreference drug product" means the product to be manufactured under an ANDA that is the subject of the patent infringement claim, a biosimilar biological product that is the product to be manufactured under the biosimilar biological product application that is the subject of the patent infringement claim, or both.

(i) "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.

(j) "Patent infringement claim" means any allegation made to a nonreference drug filer, whether or not included in a complaint filed with a court of law, that its nonreference drug product or application infringes any patent held by, or exclusively licensed to, the reference drug holder.

(k) "Reference drug holder" means either:

(1) A brand holder that is any of the following:

(A) The holder of an approved NDA for a drug product application filed under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(B) A person 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.

(C) The predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with, any of the entities described in subparagraph (A) or (B), with 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 those entities.

(2) A biological product licenseholder, which means any of the following:

(A) The holder of an approved biological product license application for a biological drug product under Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(B) A person owning or controlling enforcement of any patents that claim the biological product that is the subject of the approved biological patent license application.

(C) The predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with, any of the entities described in subparagraph (A) or (B), with 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 those entities.

(*l*) "Reference drug product" means the product to be manufactured by the reference drug holder and includes both branded drugs of the NDA holder and the biologic drug product of the biologic product license applicant.

(m) "Statutory exclusivity" means those prohibitions on the approval of drug applications under clauses (ii) through (iv), inclusive, of Section 505(c)(3)(E) (5-year and 3-year data exclusivity), Section 527 (orphan drug exclusivity), or Section 505A (pediatric exclusivity), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 360cc, and 355a, respectively) or on the licensing of biological product applications under Section 262(k)(7) of Title 42 of the United States Code (12-year exclusivity) or Section 262(m)(2) or (3) of Title 42 of the United States Code (pediatric exclusivity).

134002. (a) (1) ~~Notwithstanding any other law, and subject to paragraph (2),~~ *Except as provided in paragraph (3),* an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, shall be presumed to have anticompetitive effects and shall be a violation of this section if both of the following apply:

(A) A nonreference drug filer receives anything of value from another company asserting patent infringement, including, but not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of ~~their~~ *its* brand drug.

(B) The nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time.

(2) As used in subparagraph (A) of paragraph (1), "anything of value" does not include a settlement of a patent infringement claim in which the consideration granted by the brand or reference drug filer to the nonreference drug filer as part of the resolution or settlement consists of only one or more of the following:

(A) The right to market the competing product in the United States before the expiration of either:

(i) A patent that is the basis for the patent infringement claim.

(ii) A patent right or other statutory exclusivity that would prevent the marketing of the drug.

(B) A covenant not to sue on a claim that the nonreference drug product infringes a United States patent.

(C) Compensation for saved reasonable future litigation expenses of the reference drug holder but only if both of the following are true:

(i) The total compensation for saved litigation expenses is reflected in budgets that the reference drug holder documented and adopted at least six months before the settlement.

(ii) The compensation does not exceed the lower of the following:

(I) Seven million five hundred thousand dollars ($7,500,000).

(II) Five percent of the revenue that the nonreference drug holder projected or forecasted it would receive in the first three years of sales of its version of the reference drug documented at least 12 months before the settlement. If no projections or forecasts are available, the compensation does not exceed two hundred fifty thousand dollars ($250,000).

(D) An agreement resolving or settling a patent infringement claim that permits a nonreference drug filer to begin selling, offering for sale, or distributing the nonreference drug product if the reference drug holder seeks approval to launch, obtains approval to launch, or launches a different dosage, strength, or form of the reference drug having the same active ingredient before the date set by the agreement for entry of the nonreference drug filer. A different form of the reference drug does not include an authorized generic version of the reference drug.

(E) An agreement by the reference drug holder not to interfere with the nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product or an agreement to facilitate the nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product.

(F) An agreement resolving a patent infringement claim in which the reference drug holder forgives the potential damages accrued by a nonreference drug holder for an at-risk launch of the nonreference drug product that is the subject of that claim.

~~(2) Notwithstanding paragraph (1), parties~~

(3) Parties to an agreement are not in violation of paragraph (1) if they can demonstrate by a preponderance of the evidence that either of the following are met:

(A) The value received by the nonreference drug filer described in subparagraph (A) of paragraph (1) is a fair and reasonable compensation solely for other goods or services that the nonreference drug filer has promised to provide.

(B) The agreement has directly generated procompetitive benefits that could not be achieved by less restrictive means, and that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

(b) In determining whether the parties to the agreement have met their burden under paragraph ~~(2)~~ *(3)* of subdivision (a), the factfinder shall not presume any of the following:

(1) That entry into the marketplace could not have occurred until the expiration of the relevant patent exclusivity or that the agreement's provision for entry of the nonreference drug product before the expiration of any patent exclusivity means that the agreement is procompetitive within the meaning of subparagraph (B) of paragraph ~~(2)~~ *(3)* of subdivision (a).

(2) That any patent is enforceable and infringed by the nonreference drug filer in the absence of a final adjudication binding on the filer of those issues.

(3) That the agreement caused no delay in entry of the nonreference drug filer's drug product because of the lack of federal Food and Drug Administration (FDA) approval of that or of another nonreference drug product.

(4) That the agreement caused no harm or delay due to the possibility that the nonreference drug filer's drug product might infringe some patent that has not been asserted against the nonreference drug filer or that is not subject to a final and binding adjudication on that filer as to the patent's scope, enforceability, and infringement.

(5) This subdivision shall not be construed to preclude a party from introducing evidence regarding paragraphs (1) to (4), inclusive, and shall not be construed to preclude the factfinder from making a determination regarding paragraphs (1) to (4), inclusive, based on the full scope of the evidence.

(c) In determining whether the parties to the agreement have met their burden under paragraph ~~(2)~~ *(3)* of subdivision (a), the factfinder shall presume that the relevant product market is that market consisting of the brand or reference drug of the company alleging patent infringement and the drug product of the nonreference company accused of ~~infringement.~~ *infringement and any other biological product that is licensed as biosimilar or is an AB-rated generic to the reference product.*

~~(d) This section does not prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the brand or reference drug filer to the nonreference drug filer as part of the resolution or settlement includes only one or more of the following:~~

~~(1) The right to market the competing product in the United States before the expiration of either:~~

~~(A) Any patent that is the basis for the patent infringement claim.~~

~~(B) Any patent right or other statutory exclusivity that would prevent the marketing of the drug.~~

~~(2) A covenant not to sue on any claim that the nonreference drug product infringes a United States patent.~~

~~(3) Compensation for saved reasonable future litigation expenses of the reference drugholder, but only if both of the following are true:~~

~~(A) The total compensation for saved litigation expenses is reflected in budgets that the reference drugholder documented and adopted at least six months before the settlement.~~

~~(B) The compensation does not exceed the lower of the following:~~

~~(i) Seven million five hundred thousand dollars ($7,500,000).~~

~~(ii) Five percent of the revenue that the nonreference drugholder projected or forecasted it would receive in the first three years of sales of its version of the reference drug documented at least 12 months before the settlement. If no projections or forecasts are available, the compensation does not exceed two hundred fifty thousand dollars ($250,000).~~

~~(4) An agreement resolving or settling a patent infringement claim that permits a nonreference drug filer to begin selling, offering for sale, or distributing the nonreference drug product if the reference drug holder seeks approval to launch, obtains approval to launch, or launches a different dosage, strength, or form of the reference drug having the same active ingredient prior to the date set by the agreement for entry of the nonreference drug filer. A different form of the reference drug does not include an authorized generic version of the reference drug.~~

~~(e)~~

(d) (1) This section does not modify, impair, limit, or supersede the applicability of the antitrust laws of California as defined in

the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the unfair competition law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code), or the availability of damages or remedies provided therein. This section does not modify, impair, limit, or supersede the right of any drug company applicant to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition of the federal antitrust law or state law.

(2) If any provision of this division, an amendment made to this division, or the application of any provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this division, the amendments made to this division, and the application of the provisions of this division or amendments to any person or circumstance shall not be affected.

~~(f)~~

(e) (1) (A) Each person that violates or assists in the violation of this section shall forfeit and pay to the State of California a civil penalty sufficient to deter violations of this section, as follows:

(i) If the person who violated this section received any value due to that violation, an amount up to three times the value received by the party that is reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater.

(ii) If the violator has not received anything of value as described in clause (i), an amount up to three times the value given to other parties to the agreement reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater.

(iii) For purposes of this subdivision, "reasonably attributable to the violation" shall be determined by California's share of the market for the brand drug at issue in the agreement.

(B) Any penalty *described in subparagraph (A)* shall accrue *only* to the State of California and ~~may~~ *shall* be recovered in a civil action brought by the Attorney General in its own name, or by any of its attorneys designated by it for that purpose, against any party to an agreement that violates this section.

(2) Each party that violates or assists in the violation of this section shall be liable for any damages, penalties, costs, fees, injunctions, or other remedies that may be just and reasonable and available under the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the unfair competition law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code), as applicable.

(3) If the State of California is awarded penalties under subparagraph (A) of paragraph (1), it may not recover penalties pursuant to another law identified in paragraph (2). This section shall not be construed to foreclose the State of California's ability to claim any relief or damages available in paragraph (2), other than those that are penalties.

(4) An action to enforce a cause of action for a violation of this section shall be commenced within four years after the cause of action accrued.

SEC. 2. The provisions of this act are severable. If any provision of this act or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

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