CAHP LEGISLATIVE INFORMATION

AB 824 (Wood)
Chapter 531, Statutes of 2019

As a service to our members, the California Association of Health Plans produces guidelines designed to assist in the interpretation and implementation of new laws, and to promote full compliance with those laws. This document, however, is not intended to be authoritative. Any questions about official interpretations of the law should be directed to the appropriate state regulatory agency such as the Department of Managed Health Care or the Department of Health Care Services, as well as your legal counsel.

PRESERVING ACCESS TO AFFORDABLE DRUGS

BACKGROUND

Assembly Bill 824 was authored by Assemblymember Jim Wood, the Chair of the Assembly Health Committee. This CAHP supported bill was sponsored by Attorney General Xavier Becerra. The stated purpose of the bill was to tackle "pay-for-delay" agreements between drug companies that prevent cost-effective generic drugs from entering the market. Brand name and generic drug manufacturers entering into agreements make them presumptively anticompetitive. This bill fights this tactic and preserves consumer access to affordable drugs.

Interest groups representing both brand and generic drug manufacturers were opposed to this bill. Some opposition was removed, however, after a series of amendments. Amendments taken to the bill expand the types of agreements exempted from this bill and delete the requirement that parties prove that the procompetitive benefits of an agreement be achieved by less restrictive means.

CAHP supported this measure because the pay-for-delay tactics targeted by this bill make it harder for plans and other payers to take advantage of market alternatives that can lower costs. AB 824 received bi-partisan support in the Legislature although it was opposed by some Republicans and a few Democrats.

REQUIREMENTS

AB 824 adds Division 114.01 (commencing with Section 134000) to the Health and Safety Code, relating to business.

Specifically, AB 824 does the following:

Presumption of Anticompetitive Effects

134002. (a) (1) Requires an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, to be presumed to have anticompetitive effects and in violation of this bill if:

(A) A generic or biosimilar drug application 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 its brand drug; and,
(B) The generic or a biosimilar filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic or a biosimilar for any period of time.

Exceptions to the Presumption of Anticompetitive Effects

134002. (a) (2) Specifies that "anything of value" does not include a patent infringement claim settlement in which the consideration granted by the brand drug filer to the generic or a biosimilar filer 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 infringement claim; or, 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 generic or biosimilar drug product infringes a patent;
(C) Compensation for saved reasonable future litigation expenses of the reference drug holder, but only if: (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; and, (ii) The compensation does not exceed the lower of $7.5 million or 5% of the revenue that the generic or biosimilar filer projected or forecasted it would receive in the first three years of sales, documented at least 12 months before the settlement. If no projections or forecasts are available, the compensation does not exceed $250,000;
(D) An agreement resolving or settling a patent infringement claim that permits a generic or biosimilar filer to begin selling, offering for sale, or distributing its drug product if the brand drug holder seeks approval to launch, obtains approval to launch, or launches a different dosage, strength, or form of the brand drug having the same active ingredient before the date set by the agreement for entry of the generic or biosimilar filer. Specifies that a different form of the brand drug does not include an authorized generic version of that drug;
(E) An agreement by the brand drug holder not to interfere with the generic or biosimilar filer's ability to secure and maintain regulatory approval to market its drug product or an agreement to facilitate the generic or biosimilar filer's ability to secure and maintain regulatory approval to market its drug product; or,
(F) An agreement resolving a patent infringement claim in which the brand drug holder forgives the potential damages accrued by a generic or biosimilar drug holder for an at-risk launch of its drug product that is the subject of that claim.

134002. (a) (3) Specifies that parties to an agreement are not in violation of 1) if they can demonstrate by a preponderance of the evidence that either:

(A) The value received by the generic or a biosimilar filer is a fair and reasonable compensation solely for other goods or services that the generic or a biosimilar filer has promised to provide; or,
(B) The agreement has directly generated procompetitive benefits, and that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

134002. (b) Prohibits a jury or judge, in determining whether the parties to the agreement have met their burden, from presuming:

(1) That entry into the marketplace could not have occurred until the patent expiration or that the agreement's provision for entry of the generic or biosimilar before the expiration of any patent exclusivity means that the agreement is procompetitive consistent with 3) a)
(2) That any patent is enforceable and infringed by the generic or biosimilar maker 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 generic or because of the lack of FDA approval of that or of another generic or biosimilar; or,
(4) That the agreement caused no harm or delay due to the possibility that the generic or biosimilar might infringe some patent that has not been asserted against the generic or biosimilar maker or that is not subject to a final and binding adjudication on that filer as to the patent's scope, enforceability, and infringement.

134002. (b) (5) Prohibits this bill from being construed to preclude a party from introducing evidence regarding (4) above or from being construed to preclude a judge or jury from making a determination regarding (4) above, based on the full scope of the evidence.

134002. (c) Requires a judge or jury, in determining whether the parties to the agreement have met their burden, to presume that the relevant product market is that market consisting of the brand drug of the company alleging patent infringement and the drug of the generic or biosimilar accused of infringement and any other biological product that is licensed as biosimilar or is an AB-rated generic to the brand product.

No Impact on Existing Antitrust Laws

134002. (d) (1) Specifies that this bill does not modify, impair, limit, or supersede the applicability of the antitrust laws of California or the unfair competition law, as specified, or the availability of damages or remedies provided therein. Specifies that this bill 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.

Severability

134002. (d) (2) Requires, if any provision of this bill, an amendment made to its provisions, or the application of any provision or amendment to any person or circumstance is held to be

unconstitutional, the remainder of this bill, amendments, and the application of its provisions or amendments to any person or circumstance to not be affected.

Penalties

134002. (e) (1) (A) Requires each person that violates or assists in the violation of this bill to forfeit and pay a civil penalty sufficient to deter violations of this bill, as follows:

(i) If the person who violated this bill 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 bill, or $20 million, whichever is greater; or
(ii) If the violator has not received anything of value, an amount up to three times the value given to other parties to the agreement reasonably attributable to the violation of this bill, or $20 million, whichever is greater.
(iii) Requires "reasonably attributable to the violation" to be determined by California's share of the market for the brand drug at issue in the agreement.

134002. (e) (1) (B) Requires any penalty to accrue to the State of California and permits it to be recovered in a civil action brought by the Attorney General (AG) 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 bill.

134002. (e) (2) Requires each party that violates or assists in the violation of this bill, to be liable for any damages, penalties, costs, fees, injunctions, or other remedies that may be just and reasonable and available under the Cartwright Act, the Unfair Practices Act, or the unfair competition law, as applicable. Prohibits the State of California, if it is awarded penalties pursuant to this bill, from recovering penalties under these three laws. Prohibits this bill from being construed to foreclose the State of California's ability to claim any relief or damages other than those that are penalties.

134002. (e) (4) Requires an action to enforce a cause of action for a violation of this bill to commence within four years after the cause of action accrued.