ASSEMBLY THIRD READING
AB 824 (Wood)
As Amended May 16, 2019
Majority vote

SUMMARY:

Presumes that an agreement that resolves or settles a patent infringement claim in connection with the sale of a pharmaceutical product to be anticompetitive if both of the following apply: 1) a generic or biosimilar manufacturer receives anything of value from another company asserting patent infringement; and, 2) the generic or biosimilar manufacturer agrees to limit or forego research, development, manufacturing, or sales of the generic or biosimilar manufacturer's product for a period of time.

Major Provisions
Parties to an agreement are not in violation of this bill if they can demonstrate by preponderance of the evidence: 1) The value received by the generic/biosimilar is fair and reasonable compensation for other goods or services that the generic/biosimilar manufacturer has promised to provide; or, 2) The agreement has directly generated procompetitive benefits that could not be achieved by less restrictive means, and that the procompetitive benefits outweigh the anticompetitive effects of the agreement.

This bill allows an agreement or settlement of a patent infringement case in which the consideration granted by the brand name manufacturer to the generic as part of the settlement includes one or more of the following: 1) The right to market the competing product in the U.S. before the expiration of either any patent that is the basis for the patent infringement claim; or, 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 non-reference drug product infringes a U.S. patent

COMMENTS:

Enacted in 2003, the Medicare Prescription Drug, Improvement and Modernization Act, among other provisions, requires brand name and generic drug manufacturers to file certain agreements with the Federal Trade Commission (FTC) and the United States Department of Justice. It is through the review of these filings that has given FTC the ability to prosecute brand name and generic companies that enter into pay-for-delay agreements. According to the FTC, "to stifle competition from lower-cost generic medicines . . . drug makers have been able to sidestep competition by offering patent settlements that pay generic companies not to bring lower-cost alternatives to market. Pay-for-delay patent settlements block all other generic drug competition for a growing number of branded drugs." According to an FTC study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year. Since 2001, the FTC has filed a number of lawsuits to stop these deals, and it supports legislation to end pay-for-delay settlements.

According to the Author:
Pay-for-delay agreements hurt consumers twice – once by delaying the introduction of an equivalent generic drug that is almost always cheaper than the brand name and second by stifling additional competition because we know that when multiple manufacturers of generic drugs compete with each other, prices can be up to 90% less than what the brand name drug cost originally. This bill makes California the first state to tackle pay-for-delay agreements;

and preserves consumer access to affordable drugs by prohibiting brand name and generic drug manufacturers from entering into these types of agreements by making them presumptively anticompetitive. The high costs of prescription drugs impact not just patients but also payers such as employers and the Medicare and Medicaid Programs.

Arguments in Support:
Supporters such as Health Access of California, the California Labor Federation, and the Small Business Majority state that controlling drug prices, and ensuring competition helps consumers, businesses, and employers have access to affordable health care. Pay for delay agreements take money out of workers' pockets to unfairly increase drug company profits. In its support, the California Public Interest Research Group states that it conducted an analysis of pay-for-delay settlement in 2013 and found, among other findings, that brand-name drugs cost 10 times more than their generic equivalents, on average, and as much as 33 times more; and brand-name drug companies had made an estimated $98 billion in total sales of these drugs while the generic versions were delayed.

Arguments in Opposition:
The Association for Accessible Medicine (AAM), in its opposition, states that this bill penalizes procompetitive patent settlements that significantly expedite generic and biosimilar access. Additionally, AAM notes that there is an existing federal framework in place under FTC v. Actavis to carefully review and police patent settlements.

The Pharmaceutical Research and Manufacturers of America (PhRMA) has taken an oppose unless amended position on this bill. PhRMA indicates that this bill displaces the FTC's role in policing patent settlements, and is inconsistent with the approach in FTC v. Actavis. It seeks amendments to modify the scope to only include patent infringement claims. PhRMA also seeks amendments to allow the factfinder to make appropriate determinations based on the circumstances of the case, consistent with existing precedent and antitrust law. Finally, PhRMA requests that the private right of action provision be removed.

FISCAL COMMENTS:

According to the Assembly Appropriations Committee:

1) Although this bill only authorizes but does not require, the Department of Justice (DOJ) to take action, $1.6 million in costs to the Antitrust Section within DOJ's Public Rights Division are anticipated to pursue civil action towards violators. These costs are for additional deputy attorneys general and associated legal staff as well as legal expert witness fees and data hosting costs (Attorney General Antitrust Account; Unfair Competition Law Fund).

2) Unknown, potentially significant GF revenue from penalties or settlements.

VOTES:

ASM HEALTH: 12-0-3
YES: Wood, Mayes, Aguiar-Curry, Bonta, Burke, Carrillo, Limón, McCarty, Nazarian, Ramos, Rodriguez, Santiago
ABS, ABST OR NV: Bigelow, Flora, Waldron

ASM JUDICIARY: 10-0-2
YES: Mark Stone, Chau, Chiu, Gonzalez, Holden, Kalra, Maienschein, Obernolte, Petrie-Norris, Reyes
ABS, ABST OR NV: Gallagher, Kiley

ASM APPROPRIATIONS: 13-1-4
YES: Gonzalez, Bloom, Bonta, Calderon, Carrillo, Chau, Eggman, Gabriel, Eduardo Garcia, Maienschein, Petrie-Norris, Quirk, Robert Rivas
NO: Brough
ABS, ABST OR NV: Bigelow, Diep, Fong, Obernolte

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