Board of Administration

Agenda Item 9c

June 19, 2019

Item Name: Assembly Bill 824 (Wood) – Preserving Access to Affordable Prescription Drugs

Program: Legislation

Item Type: Action

Recommendation

Adopt a support position on Assembly Bill (AB) 824 (Wood), as amended May 16, 2019, because it may provide greater access to affordable prescription drugs for our members.

Executive Summary

AB 824 creates a legal presumption that patent infringement settlement agreements between generic and brand-name drug manufacturers are anticompetitive. Moreover, the parties that enter these agreements are subject to a civil penalty unless they can prove by a preponderance of evidence that the agreements are (1) fair and reasonable compensation solely for goods and services the generic manufacturer has agreed to provide, or (2) generate procompetitive effects.

Strategic Plan

This item supports CalPERS 2017-22 Strategic Goal “Transforming Health Care Purchasing and Delivery to Achieve Affordability.”

Background

Presently, the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, encourages a generic drug manufacturer to seek market entry prior to expiration of a brand-name drug’s patent. Generic drug manufacturers have an incentive to challenge brand-name drug patents, because the first generic drug manufacturer to file its application can obtain 180 days of market exclusivity (i.e., it has the only generic drug version of the brand-name drug on the market). To obtain Food and Drug Administration (FDA) approval for entry before patent expiration, a generic drug manufacturer may certify that its product does not infringe upon the brand-name drug’s patent or that the brand-name drug’s patent is unenforceable or otherwise invalid.

Typically, brand-name drug manufacturers challenge the generic drug manufacturer’s certification through litigation claiming patent infringement. For brand-name drug manufacturers

to prevail, they must successfully defend the validity of their patents and demonstrate that the generic drug manufacturer's product would infringe on those patents.

Brand-name drug manufacturers have been successful in delaying generic competition by agreeing to pay a generic drug competitor to hold its product off the market for a certain period. These so-called "pay-for-delay" agreements have arisen as part of patent infringement litigation settlements between brand-name and generic drug manufacturers. Consequently, brand-name drug prices stay high, and the brand-name drug and generic drug manufacturer share the benefits of the brand-name drug manufacturer's monopolistic profits. Consumers, however, are harmed as they miss out on paying for lower-priced generic drugs. For example, a brand-name medication for lowering cholesterol may cost $699 dollars, but would be available as a generic alternative for $14 at retail.

As an example of these anticompetitive practices, Assemblymember Jim Wood cites a patent infringement settlement agreement with four generic drug manufacturers to delay the release of a generic version of the sleep disorder drug Provigil into the market until 2012. For over $300 million, the pay-for-delay agreement provided "six more years of patent protection," which generated $4 billion in sales for Provigil's manufacturer. In a 2010 study, the Federal Trade Commission (FTC) noted these pay-for-delay agreements are estimated to cost consumers $3.5 billion annually – $35 billion over the next 10 years. According to the IMS Health Institute, generic drugs saved the U.S. healthcare system $1.67 trillion from 2007 to 2016.

CalPERS spends more than $2 billion per year for prescription drug benefits provided under its health plans. CalPERS has been working on strategies to mitigate the rising cost of prescription drugs for the past several years. Each year, CalPERS team members report on prescription drug utilization and cost trends. The most recent report reiterated the importance of generic and biosimilar drugs for CalPERS health plans as part of these strategies. In general, generic drugs cost less and have a lower co-pay than brand-name drugs. Use of generic drugs by CalPERS' members lead to lower costs for them and their employers.

AB 824 would make California the first state to address pay-for-delay agreements and attempts to preserve consumer access to affordable drugs by presuming that these agreements are anticompetitive unless proven otherwise. This bill is intended, in part, to expedite market entry for generic drugs and reduce brand-name drug patent-holders monopolistic behavior.

Analysis

1. Proposed Changes
   Specifically, AB 824:
   - Provides that an agreement to resolve or settle a patent infringement claim is presumed to have anticompetitive effects and shall be in violation of the bill's provisions if both of the following apply:
     - A non-reference drug filer receives payment from another company asserting patent infringement; and
     - The non-reference drug filer agrees to limit the research, development, manufacturing, marketing or sales of the non-reference drug filer's product for any period of time.

- Provides that the parties to a settlement agreement are not in violation of the bill's provisions if they can demonstrate by a preponderance of the evidence that either of the following are met:
    - The value received by the non-reference drug filer is fair and reasonable compensation solely for other goods or services that the non-reference drug filer has promised to provide; or
    - 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.
- Provides that in determining whether the parties to a settlement agreement are not in violation of the bill's provisions, the factfinder (judge or jury) shall not presume specified items.
- Provides presumptions for the factfinder regarding the relevant product market for determining whether the parties to a settlement agreement have demonstrated they are not in violation of the bill's provisions.
- Clarifies that the bill does not prohibit a resolution or settlement of a patent infringement claim if the resolution or settlement contains one or more certain items.
- Specifies that this bill does not modify, impair, limit or supersede the applicability of antitrust laws of California as defined in the Cartwright Act or the availability of damages or remedies provided under this Act.
- Provides that if any provision of the bill is held invalid or unconstitutional, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.
- Provides that each person who violates or assists in the violation of this bill's provisions shall forfeit and pay to the State of California a civil penalty sufficient to deter violations.
- Provides that any penalty shall accrue to the State of California and may be recovered in a civil action brought by the Attorney General.

2. Arguments in Support

Supporters state the bill will control drug prices and ensure competitive pricing that will help consumers, businesses, and employers have access to affordable healthcare. They argue that pay-for-delay agreements take money out of workers' pockets to unfairly increase drug company profits.

The sponsor of the bill, Attorney General Xavier Becerra, states that AB 824 aims to reduce prescription drug costs by increasing enforcement against collusive, so called pay-for-delay agreements. He adds that these agreements "allow a drug company to extend its monopoly over a brand name drug by keeping lower priced gene+ric drugs for consumers out of the market for years."

Small Business Majority argues that "prescription drug costs account for 19% of total spending in employer-sponsored coverage and are a key contributor to the steep rise in healthcare expenses" and that "prescription drug costs have been rising at a faster rate than overall medical costs."

3. Arguments in Opposition
   Opponents argue that the bill will chill procompetitive settlements, augmenting costs to drug companies due to litigation. Opposing groups also contend that the bill creates a new private right of action, changes the evidentiary standard for antitrust litigation in California, and may be preempted or unconstitutional by federal law.

   Pharmaceutical Research and Manufacturers of America states the bill would alter the legal framework surrounding patent settlement agreements and that "[d]eterring procompetitive patent settlements could also lead to delayed generic entry by forcing generic companies to take complex patent challenges all the way to a court decision, risking that the competing generic medicine remains off the market entirely until patent expiration."

   Biocom expressed it is "greatly concerned about the change of evidentiary standard to one that begins with a presumption of wrong-doing on the part of the involved parties. This concept is akin to forcing an involved party to disprove a negative statement."

Budget and Fiscal Impacts

1. Benefit Costs
   AB 824 may create greater generic drug availability and keep health plan premiums and out-of-pocket costs affordable and sustainable for CalPERS' members and employers.

2. Administrative Costs
   No additional cost to CalPERS.

Benefits and Risks

1. Benefits
   - It potentially increases the number of generic drug manufacturers, which may lead to more competition in this market segment.
   - It may decrease overall healthcare costs for members and employers.
   - It supports CalPERS 2017-22 Strategic Goal "Transforming Health Care Purchasing and Delivery to Achieve Affordability."

2. Risks
   - It potentially increases litigation, which may impact the costs for prescription drugs.

Attachments

Attachment 1 – Support & Opposition

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