SB 764 A -A6 STAFF MEASURE SUMMARY

House Committee On Health Care

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Meeting Dates: 5/18, 5/20, 5/27

WHAT THE MEASURE DOES:

Requires court to presume that a resolution agreement that ends a dispute over an alleged infringement of a patent, or a violation of other protection for a protected drug, has anticompetitive effects if alleged infringer receives item of value or agrees to limit or stop researching, developing, manufacturing, marketing or selling a competing drug. Specifies basis on which party to resolution agreement may overcome presumption. Authorizes Attorney General to bring action to recover civil penalty for violations in amount that is equivalent to three times value of item that alleged infringer received or $10 million, whichever is greater.

Senate Vote: *Passed. Ayes, 16; Nays, 12 (Anderson, Boquist, Findley, Girod, Hansell, Johnson, Kennemer, Knopp, Linthicum, Robinson, Thatcher, Thomsen); Excused, 2 (Frederick, Heard)*

REVENUE: No revenue impact

FISCAL: Has minimal fiscal impact

ISSUES DISCUSSED:

- Operation and impacts of drug patent infringement settlement agreements
- Potential impacts on generic drug availability
- Applicability of current antitrust laws
- Federal regulation and legal treatment of settlement agreements

EFFECT OF AMENDMENT:

-A6 **Replaces measure.** Modifies definitions of "competing drug," and "item of value." Modifies circumstances in which resolution agreements may overcome presumption of anticompetitive effects. Takes effect on the 91st day following adjournment sine die.

BACKGROUND:

Patent rights play an important role in the development and pricing of pharmaceutical products by granting the holder of a valid patent a temporary monopoly on new and innovative drugs. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act") to foster drug innovation and competition. The Act created mechanisms to increase competition by generic drugs, including a shortened Food and Drug Administration (FDA) approval process for generic drugs and a method for generic firms to challenge the patents covering innovative drugs, along with incentives for bringing such challenges. This shortened process allows generic firms to file an abbreviated new drug application (ANDA) that demonstrates their drug is bioequivalent to the innovative drug and can rely on the clinical trials performed for the innovative drug to demonstrate safety and effectiveness. The generic firm can also certify that the patents covering the innovative drug are invalid and/or will not be infringed by the generic (a.k.a. a "Paragraph IV certification").

The Hatch-Waxman Act incentivizes generic firms to bring patent challenges by awarding 180 days of exclusivity to the first Paragraph IV filer upon the successful resolution of patent infringement litigation. Most settlements of Paragraph IV patent infringement litigation involve some restriction on generic entry, often with a patent-term split agreement that allows the generic firm to enter the market on a date that is earlier than the expiration date of the brand manufacturer's patent. In 2013, the United States Supreme Court decided in *FTC v. Actavis* that

settlements in patent infringement litigation are not immune from antitrust scrutiny and that the anticompetitive effects of these agreements could be found unlawful using a "Rule of Reason" framework for evaluating the settlement. In 2019, California enacted Assembly Bill 824, which rendered certain pharmaceutical patent litigation settlement agreements presumptively anticompetitive.

Senate Bill 764 A requires the Attorney General and courts to presume as anticompetitive specified prescription drug resolution agreements.