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Cover Page Footnote

J.D. candidate, May 2021, Loyola Law School, Los Angeles. Sincere thanks to Professor Brietta Clark whose comments and perspective contributed to the clarity of this Note and my understanding of healthcare issues. Thank you as well to the diligent editors and staff of the Loyola of Los Angeles Law Review, especially Adam Peterson for his guidance through this process. I am additionally grateful to the professors who graciously advised on specific areas of law—Professor Robin Feldman on reverse payment settlements, Professor Justin Levitt on the dormant commerce clause, and Professor Lee Petherbridge on preemption and patent law. My interest in competition law and policy was encouraged by Frances Marshall, a thoughtful mentor. I would also like to acknowledge the support of Melissa Campos and the important insights provided by colleagues during the writing of this Note, especially Christopher Riley, Elizabeth Berry, Alexandra Maher, Shannon Leap, Eda Harotounian, Christopher Kissel, Alexander Hofmann, and Scott Limbacher. Finally, thanks to my parents, sister, and anyone else reading this.

SHIFTING THE BURDEN ON PAY-FOR-DELAY CHALLENGES: ANALYZING AB 824'S EFFECTS ON REVERSE PAYMENT SETTLEMENTS AND DRUG COSTS

*Kevin Wallentine**

Antitrust scholars and agencies have recognized the anticompetitive impact of reverse payment settlements—in which branded and generic drug companies settle patent disputes, typically by delaying the entry of generics into the market. Despite clear competition concerns, these settlements are typically subject to a rule of reason analysis that puts the burden on enforcers and plaintiffs to prove their anticompetitive harms. Recent California legislation—AB 824—shifts the burden to the settling drug companies to prove their arrangement is not anticompetitive. AB 824 presents an opportunity for advocates of lower drug costs but still faces hurdles and shortfalls. This Note examines the efficacy of the legislation, the likelihood of it surviving pending constitutional challenges, and how it fits into broader efforts at lowering drug costs for consumers.

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I. INTRODUCTION

A branded drug company charges consumers monopoly prices for its patented drug, enabled by a federal law that creates patent exclusivity for a defined period of time. Spurred by other federal legislation that permits the entry of generic competitors, a generic drug company plans to enter the market. Concerned about the threat to its monopoly power, the branded company sues the generic company for infringement. Before reaching trial, the parties reach an agreement in which the branded company will compensate the generic company to keep its drug off the market. The branded company benefits from the extension of its monopoly power, the generic company benefits from the compensation provided by the settlement, and patients continue to pay a premium.

This scenario looks like a classic restraint of trade, but is there antitrust liability for these companies? Between 2005 and 2013, many courts found no antitrust violations in these "pay-for-delay" settlements.[1] Following the Supreme Court's decision in *Federal Trade Commission v. Actavis, Inc.*,[2] courts have applied a "rule of reason" analysis, but this analysis can be "complex and burdensome" and could allow anticompetitive deals to slip through.[3] In the reverse payment context, the rule of reason—discussed more thoroughly in Part II(E) of this Note—places the burden on enforcers and plaintiffs to show that the generic "agreed to abstain from using the patented innovation" and that there is an "unexplained payment" from the branded drug company to the generic drug company.[4]

California's recently passed legislation (Assembly Bill 824 (AB 824)), alternatively, shifts the burden to the settling companies to prove their arrangement is not anticompetitive.[5] Although this

1. *See* Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, Fed. Trade Comm'n 1 (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf [hereinafter Pay-for-Delay Study]; *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), *abrogated by* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136 (2013); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *abrogated by* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136 (2013).

2. 570 U.S. 136 (2013).

3. *Id.* at 144, 156; Robin Cooper Feldman, *Defensive Leveraging in Antitrust*, 87 GEO. L.J. 2079, 2107, 2112 (1999).

4. Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 259 (2019); Aaron Edlin et al., *Activating* Actavis, 28 ANTITRUST 16, 17–18 (2013).

5. Assemb. B. 824, 2019–2020 Reg. Sess. (Cal. 2019).

represents a leap forward for enforcers traditionally required to satisfy a rule of reason analysis, it still comes with its own challenges and questions. This Note will examine the state of play of reverse payment arrangements, analyze how the recent California legislation compares with common law and statutory antitrust provisions, and assess whether this legislation can effectively combat pay-for-delay settlements that extract large tolls from consumers.

Part II will discuss the structure of pay-for-delay arrangements, the evolving state of the law related to pay-for-delay arrangements, and the role of antitrust agencies in policing pay-for-delay settlements. Part III will discuss the efficacy of AB 824, including potential pitfalls, constitutional challenges to the law, and how this legislation is situated within the overall proposals for pharmaceutical reform.

II. BACKGROUND

A. Structure of Pay-For-Delay Arrangements

While the precise terms vary from settlement to settlement, the general structure of pay-for-delay arrangements is a quid pro quo between branded drug companies and generic drug companies.[6] After the branded drug company files an infringement suit against the generic, it provides something of value—traditionally, a monetary settlement—to the generic drug company.[7] However, this settlement appears less like a traditional litigation settlement and more like an agreement between competitors to restrain trade.[8] The generic drug company agrees to delay the market entry of its competing product for a certain amount of time.[9] The branded drug company thus remains able to charge consumers higher prices while the generic receives a portion of these monopoly profits. This arrangement allows both parties to benefit while externalizing the costs to consumers.[10]

B. Dueling Legislative Policy Goals Permitting Pay-For-Delay

These reverse payment arrangements, and the toll they take on consumers, stem from competing policy goals and legislative

6. *See* Feldman & Misra, *supra* note 4, at 249.
7. *See id.*
8. *See id.* at 257.
9. *Id.* at 249.
10. *See id.* at 256.

frameworks. In hopes of incentivizing innovation, the United States currently allows twenty-year patent protection.[11] Further, certain drugs have exclusivity periods that bar competitors from entering the market.[12] These protections are in place to allow pharmaceutical companies to recover research and development costs.[13] Limiting the market in this way, however, has the potential to create monopolies and price patients out of purchasing necessary drugs.[14]

While maintaining these protections for patented drugs, Congress has also attempted to rein in drug costs. The Drug Price Competition and Patent Term Restoration Act—commonly known as the Hatch-Waxman Act—promotes this goal by encouraging the entrance of lower-cost generic drugs that compete with the higher-priced branded drugs.[15] This market entrance is facilitated by allowing the generic applicant to use the branded drug's trials to demonstrate its own safety through the abbreviated new drug application (ANDA) process.[16] ANDA thus relieves generic companies of costly drug trials that represent a high barrier to entry. The first generic to file and obtain this approval gains a 180-day exclusivity period, creating a six-month

11. 35 U.S.C. § 154(a)(2) (2018) ("[S]uch grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . . ."); *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#howlongpatentterm (last visited Oct. 4, 2020).

12. *Frequently Asked Questions on Patents and Exclusivity*, *supra* note 11.

13. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1562–63, 1562 n.25 (2006) ("For blockbuster drugs as with blockbuster films, the ability to legally exclude rivals from offering a copy preserves the return from a massive initial investment."); Feldman & Misra, *supra* note 4, at 254–55.

14. Aaron S. Kesselheim et al., *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and Avenues for Improvement*, 30 STAN. L. & POL'Y REV. 421, 453 (2019) ("Once a drug is approved, the brand-name manufacturer sets its initial price in the United States at what the manufacturer estimates that the market will bear. . . . As a result, most brand-name drugs cost far more in the United States than in other comparable settings around the world. Another distinct feature of the U.S. market is that manufacturers tend to increase prices over time prior to expiration of market exclusivity even in the absence of new information about the drug's value.").

15. Feldman & Misra, *supra* note 4, at 253; Hemphill, *Paying for Delay*, *supra* note 13, at 1565; *see also* Patent Drug Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. ch. 9).

16. Feldman & Misra, *supra* note 4, at 254; 21 U.S.C. § 355(j) (2018).

duopoly where only the generic and branded drugs compete.[17] Securing this approval and exclusivity is usually lucrative for generic manufacturers, potentially allowing revenues of several hundred million dollars.[18]

A generic applying through ANDA and planning to compete with a branded drug must submit a certification, which includes a statement that the branded drug's patent is "invalid or will not be infringed by the manufacture, use, or sale" of the generic.[19] But filing this application constitutes an actionable infringement of the branded drug's patent.[20] The ostensible goal was to allow generics to resolve potential infringement claims and challenge weak patents, rather than be found to have infringed after the costly process of bringing the drug to market.[21] This permits branded drug companies to sue their potential generic competitors and serves as the basis for pay-for-delay settlements.

C. Pay-For-Delay Benefits and Costs

A challenge to the branded drug's monopoly has the potential to cost its manufacturer billions of dollars.[22] Though generics have had a 73 percent success rate in cases where they have challenged branded drugs, there is always uncertainty in patent litigation, and a generic drug's immediate rollout comes with costs to its manufacturer.[23] A

17. 21 U.S.C. § 355(j)(5)(B)(iv); Feldman & Misra, *supra* note 4, at 255 ("[I]f the generic wins and the branded drug patents are invalidated, duopoly between the generic drug and the branded drug will begin immediately, potentially costing the brand manufacturer billions of dollars . . . .").

18. Hemphill, *Paying for Delay*, *supra* note 13, at 1579.

19. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* Feldman & Misra, *supra* note 4, at 254; Hemphill, *supra* note 13, at 1565.

20. 35 U.S.C. § 271(e)(2)(A) (2018); Hemphill, *Paying for Delay*, *supra* note 13, at 1566. Such infringement, however, does not make the generic manufacturer liable for damages. *See* Feldman & Misra, *supra* note 4, at 254 ("While the expense and risk of litigation is a deterrent to the generic companies, they do not face liability for damages from sales of the product, if the patent is found valid given that they have not actually engaged in any sales.").

21. Motion and Brief of Representative Henry A. Waxman as Amicus Curiae in Support of Petitioner at 7, Fed. Trade Comm'n v. Schering-Plough Corp., 548 U.S. 919 (2005) (No. 05-273), 2005 WL 2462026, at *7.

22. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 635 (2009) ("The two drug makers have a powerful incentive to settle. For a blockbuster drug with billions of dollars in annual sales, a brand-name firm has billions to lose from generic competition.").

23. FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY vi (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-

settlement providing immediate benefits to generic manufacturers and extending the branded manufacturer's monopoly creates substantial benefits for both parties.[24]

This resolution is mutually beneficial to the parties—branded drug companies and generic drug manufacturers. However, it externalizes costs to third parties by burdening patients and insurance companies with unnecessarily extended monopoly prices. In 2009, Federal Trade Commission (FTC) Commissioner Jon Leibowitz calculated that "a conservative estimate of potential savings [for consumers] from a ban on pay for delay settlements" amounted to $3.5 billion per year.[25] Another study found that a one-year delay in the generic's market entry represented a consumer cost of approximately $12 to $14 billion.[26] This study also highlighted the welfare loss resulting from the changes to consumers' and insurance companies' purchasing decisions.[27]

D. Antitrust Laws and Agency Enforcement

The traditional bases for federal antitrust enforcement are the Sherman Act of 1890, the Clayton Act of 1914, and the Federal Trade Commission Act of 1919 ("FTC Act").[28] "To establish liability under [section 1 of the Sherman Act], a plaintiff must prove (1) the existence of an agreement, and (2) that the agreement was in unreasonable restraint of trade."[29] Proving a Sherman Act section 2 monopolization violation requires showing: "(a) the possession of monopoly power in the relevant market; (b) the willful acquisition or maintenance of that power; and (c) causal 'antitrust' injury."[30] Section 7 of the Clayton

prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf ("Generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute.").

24. Hemphill, *Paying for Delay*, *supra* note 13, at 1580–81.

25. Jon Leibowitz, Chairman, Fed. Trade Comm'n, Speech at the Center for American Progress, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (the $35 Billion Solution) 14 (June 23, 2009), https://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements-pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf [hereinafter Leibowitz Speech].

26. Hemphill, *An Aggregate Approach to Antitrust*, *supra* note 22, at 650.

27. *Id.* at 636.

28. 15 U.S.C. §§ 1–7 (2018); *id.* §§ 12–27; *id.* §§ 41–58.

29. Aerotec Int'l, Inc. v. Honeywell Int'l, Inc., 836 F.3d 1171, 1178 (9th Cir. 2016).

30. Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 998 (9th Cir. 2010) (quoting Cal. Comput. Prods., Inc. v. Int'l Bus. Machs. Corp., 613 F.2d 727, 735 (9th Cir. 1979)).

Act prohibits acquisitions when "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."[31] The FTC Act empowers the FTC to bring antitrust law enforcement suits on its own authority.[32] These laws create clear avenues to antitrust enforcement and empower agencies to sue. However, as discussed below, the difficulty in preventing these agreements lies in courts' abilities to detect anticompetitive behavior and reticence to challenge the state-sanctioned monopoly created by the branded drug company's patents.[33]

Antitrust agencies have applied these laws and taken action at the federal and state levels. In recent years, the FTC has brought several pay-for-delay cases through federal court and administrative complaints.[34] In these cases, the FTC has sought injunctions against similar future agreements and declarations that the companies have violated anti-monopolization laws within the FTC Act.[35] Successful FTC cases produced orders stipulating that the generic and branded parties will refrain from entering into similar agreements without the consent of the FTC.[36] At the state level, the California Department of Justice recently achieved settlements in cases related to three

31. 15 U.S.C. § 18.

32. *Id.* § 45(a).

33. *See, e.g.*, Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 141 (2013) (reviewing an 11th Circuit decision that found a pay-for-delay settlement was "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent" (quoting Fed. Trade Comm'n v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd*, 570 U.S. 136 (2013))).

34. *See Pay-for-Delay: When Drug Companies Agree Not to Compete*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay (last visited Oct. 4, 2020); *see, e.g.*, Fed. Trade Comm'n v. Allergan PLC, No. 17-cv-00312-WHO, 2017 U.S. Dist. LEXIS 66042 (N.D. Cal. Apr. 5, 2017); *Impax Laboratories, Inc., In the Matter of*, FED. TRADE COMM'N, https://www.ftc.gov/enforcement/cases-proceedings/141-0004/impax-laboratories-inc (last updated Aug. 2, 2019); Stipulated Order for Permanent Injunction and Equitable Monetary Relief at 1, Fed. Trade Comm'n v. Cephalon, Inc., No. 2:08-cv-02141-MSG (E.D. Pa. June 17, 2015) [hereinafter Cephalon, Inc. Stipulated Order for Permanent Injunction].

35. *See, e.g.*, Complaint for Injunctive and Other Equitable Relief at 2, 26–27, Fed. Trade Comm'n v. Allergan PLC, No. 17-cv-00312-JCS (N.D. Cal. Jan. 23, 2017); 15 U.S.C. § 53(b) ("Whenever the Commission has reason to believe—(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice.").

36. *See, e.g.*, Cephalon, Inc. Stipulated Order for Permanent Injunction, *supra* note 34, at 9.

pharmaceutical companies.[37] These settlements enjoined the generic and branded parties from entering into similar arrangements and collected approximately $70 million in compensation for consumers.[38]

E. Federal Caselaw on Pay-For-Delay Settlements: Before and After Actavis

Early challenges to pay-for-delay arrangements found some success. In one such case, the Sixth Circuit found an arrangement where a branded company expressly paid a generic rival not to enter the market "a horizontal market allocation agreement and, as such . . . *per se* illegal under the Sherman Act and under the corresponding state antitrust laws."[39]

In this instance, however, the court noted that the facts were relatively straightforward.[40] The "naked, horizontal restraint of trade," presumed to reduce competition and harm consumers, led the court to find the settlement was per se illegal.[41]

The mid-2000s, however, saw appellate courts failing to recognize the anticompetitive implications of pay-for-delay arrangements.[42] In a case where the branded company agreed to pay a minimum of $60 million in licensing fees to a generic manufacturer to keep the generic drug from the market, the Eleventh Circuit held that there was no per se antitrust violation possible from this pay-for-delay settlement.[43] While recognizing the "effect of agreements that employ extortion-type tactics to keep competitors from entering the market," the court found that "[i]n the context of patent litigation . . . the anticompetitive effect may be no more broad than the patent's own exclusionary power."[44] The Eleventh Circuit was also concerned that

37. Press Release, State of Cal. Dep't of Just., Off. of the Att'y Gen., Attorney General Becerra Secures Nearly $70 Million Against Several Drug Companies for Delaying Competition and Increasing Drug Prices (July 29, 2019), https://oag.ca.gov/news/press-releases/attorney-general-becerra-secures-nearly-70-million-against-several-drug [hereinafter Attorney General Becerra Press Release] (at the state level, the California Department of Justice recently achieved settlements in cases related to three pharmaceutical companies, Teva, Endo, and Teikoku).

38. *Id.*

39. *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 900 (6th Cir. 2003).

40. *Id.* at 911.

41. *Id.*

42. Pay-for-Delay Study, *supra* note 1, at 1.

43. Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1060, 1065, 1076 (11th Cir. 2005).

44. *Id.* at 1064.

exposing "those agreements to antitrust liability would 'obviously chill such settlements.'"[45]

In the wake of this decision, other courts similarly subjected pay-for-delay arrangements to lower levels of antitrust scrutiny.[46] The Second Circuit "decline[d] to conclude . . . that reverse payments are *per se* violations of the Sherman Act . . . . [and] that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation."[47] The Federal Circuit similarly found that a district court was correct in not presuming a pay-for-delay arrangement to be per se unlawful, as "[o]nly agreements that have a 'predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit' are deemed to be per se unlawful."[48] The court added that per se unlawfulness "is appropriate '[o]nce experience with a particular type of restraint enables the Court to predict with confidence that the rule of reason will condemn it.'"[49] Courts during this era refused to see the clear anticompetitive effects of branded monopolies paying off potential competitors. As a result, during the six-year period from 2004 to 2009, pay-for-delay settlements increased from zero per year to nineteen per year.[50]

Antitrust scrutiny increased with the Supreme Court's 2013 *Actavis* decision. In *Actavis*, the Court reviewed an Eleventh Circuit decision involving a pay-for-delay arrangement between generic manufacturers Actavis and Paddock and branded drug manufacturer Solvay.[51] After Solvay acquired approval of a new branded drug in 2000, and a patent for its drug in 2003, Actavis and Paddock filed ANDA certifications stating that Solvay's patent was invalid and their generics did not infringe.[52] Following the typical pay-for-delay

45. *Id.* (quoting Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1309 (11th Cir. 2003)).

46. *See* Pay-for-Delay Study, *supra* note 1, at 1; *see, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), *abrogated by* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136 (2013); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *abrogated by* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136 (2013).

47. *In re Tamoxifen Citrate*, 466 F.3d at 206.

48. *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1331–32 (alteration in original) (quoting State Oil Co. v. Khan, 522 U.S. 3, 10 (1997)).

49. *Id.* at 1332 (alterations in original) (quoting *State Oil*, 522 U.S. at 10).

50. Pay-for-Delay Study, *supra* note 1, at 1.

51. *Actavis*, 570 U.S. at 144–45.

52. *Id.* at 144.

pattern, Solvay sued Actavis and Paddock.[53] Actavis's generic ANDA application was approved and received first-to-file exclusivity.[54] However, the parties settled Solvay's suit in 2006.[55] The terms of this settlement required Actavis to "not bring its generic to market until August 31, 2015, 65 months before Solvay's patent expired (unless someone else marketed a generic sooner)."[56] The settlement also required Actavis to promote Solvay's branded drug.[57] The other generic drug parties agreed to similar obligations and delays.[58] In return, Actavis received $19 million to $30 million annually for nine years from Solvay while the other generic companies received totals between $12 million and $60 million.[59]

In its decision, the Eleventh Circuit found that pay-for-delay settlements were "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[60] Reversing this decision, the Supreme Court held that "reverse payment settlements such as the agreement alleged in the complaint before us can *sometimes* violate the antitrust laws."[61] While allowing these actions to be brought, the Court did not find pay-for-delay settlements per se illegal or raise the level of scrutiny beyond a rule of reason analysis.[62]

A rule of reason analysis "requires a detailed and laborious inquiry which is described by courts and commentators as complex and burdensome on litigants and the judicial system."[63] In applying the rule of reason to pay-for-delay arrangements, some courts have followed a burden-shifting approach that requires plaintiffs to prove that the generic "agreed to abstain from using the patented innovation" and that there is an "unexplained payment" from the branded drug

53. *Id.* at 145.
54. *Id.*
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.* at 141 (quoting Fed. Trade Comm'n v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd*, 570 U.S. 136 (2013)).
61. *Id.* (emphasis added).
62. Feldman & Misra, *supra* note 4, at 258.
63. Feldman, *supra* note 3, at 2107.

company to the generic drug company.[64] Finding an unexplained payment requires:

> (a) valuing any consideration flowing from the patentee to the claimed infringer, which may be made over time and may take forms other than cash; (b) deducting from that payment the patent holder's avoided litigation costs; and (c) deducting from that payment the value of goods, services, or other consideration provided by the claimed infringer to the patent holder as part of the same transaction (or linked transactions).[65]

If these calculations result in a positive sum, it supports a finding of an unexplained payment that anticompetitively blocks the generic's entry.[66]

This calculation presents several challenges. First, difficult calculations—including the estimation of payments versus litigation costs—underpin the analysis.[67] Parties seeking to maintain the benefits of that pay-for-delay system also have the incentive to complicate agreements to disguise the structure of payments.[68] Additionally, assertion of privileges hinders external investigation of the settlements.[69] The rule of reason standard therefore presents a high hurdle for enforcers seeking to challenge these arrangements.

F. Current Pay-For-Delay Arrangements: Growing Complexity

Despite the attention pay-for-delay settlements have gotten over the past decade and post-*Actavis* antitrust scrutiny, the total number of

64. Feldman & Misra, *supra* note 4, at 259; *see also* Edlin et al., *supra* note 4, at 17–18.
65. Edlin et al., *supra* note 4, at 18.
66. *Id.*
67. Feldman & Misra, *supra* note 4, at 260.
68. *Id.*
69. *Id.*

settlements has continued to rise.[70] During the 2015 fiscal year, branded and generic drug companies filed a total of 170 settlements.[71]

Additionally, drug companies have used more complex arrangements to avoid detection and evade liability.[72] The FTC's own categorization of different pay-for-delay settlement forms has shifted completely over the past decade.[73] In the most recent FTC reports from 2013 to 2015, the FTC has included a category where the exchange between the branded and generic companies only presents *possible* compensation.[74]

Outside of the FTC's classification, Professor Robin Feldman and Research Fellow Prianka Misra identified their own "X category" that consists of arrangements where generic entry is delayed but no apparent value is exchanged.[75] This category accounted for 74 percent of settlements in 2015.[76] In examining where the value to generics might lie in such arrangements, Feldman and Misra analogize to the FTC's recent recognition of the anticompetitive potential of declining royalty provisions in settlements.[77] These provisions commit a generic to paying royalties unless the branded company launches its own generic.[78] As with declining royalty provisions, there may be further complex elements within opaque settlements that provide value to the generics.[79]

Beyond questions of immediate value to the parties, a potential anticompetitive threat in branded-generic settlements is the increased

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70. *See* FED. TRADE COMM'N: BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 1 (2017), https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/overview_of_fy_2015_mma_agreements_0.pdf [hereinafter REPORT ON AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION] ("Consistent with FY 2014, the number of settlements potentially involving pay for delay continues to decrease significantly in the wake of the Actavis decision, even though the total number of settlements filed with the FTC has increased.").

71. *Id.*

72. *See* Feldman & Misra, *supra* note 4, at 252–53.

73. *Id.* at 262–63.

74. *Id.* at 263; REPORT ON AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION, *supra* note 70.

75. Feldman & Misra, *supra* note 4, at 264.

76. *Id.*

77. *Id.* at 265–66.

78. *Id.* at 265.

79. *Id.* at 265–66.

prevalence of acceleration clauses, which allow the generic to hasten entry based on conditions like the entry of an authorized generic or another generic product.[80] Such acceleration clauses were found in approximately 76 percent of settlements in a recent year.[81] While greater generic entry typically encourages competition, acceleration clauses instead discourage other generics from entering the market due to the imminent entry of the generic that settled.[82]

In addition, the rise of biologic and biosimilar drugs presents further challenges. Biologic drugs (such as Humira) are large, complex-molecule drugs that are typically composed of hundreds of atoms, in contrast to the small-molecule drugs (such as Nexium) that are composed of less than one hundred atoms.[83] Biologic drugs have also been a key factor in rising drug costs.[84] Biosimilar drugs, which act as a lower-cost alternative to the branded biologic drugs, account for a growing percentage of pharmaceutical industry revenue and expenses.[85] Given the different regulations for biosimilars and the growth of this sector, there is the potential that an increasing portion of pay-for-delay settlements are going underreported as well.[86] While enforcers have attacked the more traditional cash-for-delay settlements, clear challenges exist to discovering and policing new forms of quid pro quo arrangements that keep cheaper generics from the market.

G. Federal Pay-For-Delay Legislation Impasse

Recognizing these complexities and that "[c]ompetition among drug makers is critical to lowering the price of prescription

80. Laura Karas et al., *Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L.J. 959, 965 (2020).

81. *Id.* at 966.

82. *Id.* at 965–66; *see also* Michael A. Carrier, *Payment After* Actavis, 100 IOWA L. REV. 7, 40–41 (2014).

83. *See Small Molecules, Large Biologics and the Biosimilar Debate*, ARIZ. BIOINDUST. ASS'N, https://www.azbio.org/small-molecules-large-biologics-and-the-biosimilar-debate (last visited Oct. 4, 2020).

84. Avik Roy, *Biologic Medicines: The Biggest Driver of Rising Drug Prices*, FORBES (Mar. 8, 2019, 8:20 PM), https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/?sh=3eae873918b0 ("In 2017, according to data from the IQVIA Institute, biologic drugs represented 2 percent of all U.S. prescriptions, but 37 percent of net drug spending. Since 2014, biologic drugs account for nearly all of the growth in net drug spending: 93 percent of it, in fact.").

85. Feldman & Misra, *supra* note 4, at 266–73.

86. *Id.* at 272.

medications," U.S. senators drafted legislation targeting pay-for-delay arrangements.[87] In January 2017, Senators Amy Klobuchar and Chuck Grassley—members of the Senate Subcommittee on Antitrust, Competition Policy, and Consumer Rights—introduced bill S.124, the Preserve Access to Affordable Generics Act.[88] The bill created a presumption that agreements in which generic ANDA filers receive "anything of value" are anticompetitive.[89] The bill included an exception if "the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."[90]

After S.124 failed to move past a referral to the Senate Judiciary Committee, a similar bill was introduced in December 2018 as S.3792—the Preserve Access to Affordable Generics and Biosimilars Act.[91] Apart from adding that biosimilars would be scrutinized along with ANDA generics, the bill largely remained the same.[92] Since its introduction, no further action has been taken on this bill. Additionally, no other state has adopted specific pay-for-delay legislation, making California a bellwether for this issue.[93]

H. California State Legislation

1. Existing Antitrust Framework

In addition to the federal antitrust law, California attorneys general have utilized state competition laws to target pay-for-delay schemes. In their complaint against Teva Pharmaceutical Industries, Cephalon, and Barr Laboratories, California Department of Justice attorneys alleged both "restraint of trade in violation of the Cartwright Act" and "violation of the Unfair Competition Law."[94]

87. Samantha DiGrande, *Klobuchar and Grassley Reintroduce Legislation to Address Pay-For-Delay Tactics*, AM. J. MANAGED CARE (Jan. 16, 2019), https://www.centerforbiosimilars.com/news/klobuchar-and-grassley-reintroduce-legislation-to-address-payfordelay-tactics.

88. S.124, 115th Cong. (2017).

89. *Id.*

90. *Id.*

91. S.3792, 115th Cong. (2018).

92. *Id.*

93. *See* Brenda Sandburg, *California's Pay-for-Delay Law May Be Harsher than FTC Regulation, Could Face Legal Challenge*, PINK SHEET (Oct. 8, 2019), https://pink.pharmaintelligence.informa.com/PS140981/Californias-PayForDelay-Law-May-Be-Harsher-Than-FTC-Regulation-Could-Face-Legal-Challenge.

94. Complaint at 24, 26, California v. Teva Pharm. Indus., Ltd., No. 2:19-cv-03281-MSG (E.D. Pa. July 29, 2019).

The Cartwright Act, California's principal antitrust law, prohibits the "combination of capital, skill or acts" to "create or carry out restrictions in trade or commerce" and other forms of anticompetitive behavior.[95] The Unfair Competition Law prohibits "unfair competition" including "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising."[96] To show that a business act is "unfair," plaintiffs "must show the conduct 'threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition.'"[97]

Both of these create private and public causes of action, and their existence is noted in the text of AB 824.[98] However, the lack of an explicit definition for which acts are anticompetitive and implicate antitrust law creates the potential for anticompetitive behavior to slip by unchallenged.

2. AB 824 Legislative Process

Currently, no state legislature has specifically targeted pay-for-delay arrangements.[99] In February 2019, State Assembly member Jim Wood introduced his Preserving Access to Affordable Drugs AB 824 in partnership with Attorney General Xavier Becerra.[100] On March 27,

95. CAL. BUS. & PROF. CODE § 16720 (Deering 2020).

96. *Id.* § 17200.

97. Byars v. SCME Mortg. Bankers, Inc., 135 Cal. Rptr. 2d 796, 804–05 (Ct. App. 2003) (quoting Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co., 973 P.2d 527, 544 (Cal. 1999)).

98. Assemb. B. 824, 2019–2020 Reg. Sess. (Cal. 2019) ("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.").

99. Melody Gutierrez, *California Could Be First State to Bar Drug Makers from Paying Competitors to Delay Release*, L.A. TIMES (Feb. 20, 2019, 4:10 PM), https://www.latimes.com/politics/la-pol-ca-drug-companies-pay-for-delay-generic-phama-20190220-story.html.

100. *See* CAL. ASSEMB., HISTORY OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess. (Cal. 2019); Press Release, Assemblymember Jim Wood, Assemblymember Wood and Attorney General Becerra Announce Bill to Outlaw "Pay for Delay" Tactics of Drug Companies (Feb. 20, 2019),

2019, AB 824 was unanimously passed by the Assembly Health Committee.[101] In the Assembly Judiciary Committee, the bill was passed after amendments that: 1) clarified "the penalty received by the State does not exceed the amount attributable to the violation based on California's share of the market, or $20 million, whichever is greater," and 2) "ensure[d] . . . the State does not receive penalties twice for the same infraction (i.e. through both the provisions of this bill and through other existing California antitrust laws)."[102] During review by the Appropriations Committee, the bill was amended to modify the standard to require parties to prove they are not in violation by a "preponderance of the evidence" rather than "clear and convincing evidence."[103] The bill was then passed as amended by the Assembly.[104]

The Senate Judiciary Committee made two major amendments. First, it created a statute of limitations—an action must be brought within four years of the cause of action accruing.[105] Second, the Judiciary Committee added two additional carve-outs to section 134002(d), which outlines settlements that are not prohibited by the bill.[106] The first carve-out allows for "compensation for saved reasonable future litigation expenses of the reference drug holder" where the drugholder's documented and adopted budgets reflect this

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https://a02.asmdc.org/press-releases/20190220-assemblymember-wood-and-attorney-general-becerra-announce-bill-outlaw-pay [hereinafter Assemblymember Jim Wood Press Release].

101. HISTORY OF ASSEMBLY BILL NO. 824.

102. ASSEMB. COMM. ON JUDICIARY, ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 6 (Cal. 2019) (as amended in Assembly, Apr. 9, 2019); Assemb. B. 824 (adding "up to . . . twenty million dollars . . . whichever is greater" and "[i]f 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").

103. *Compare* ASSEMB. COMM. ON APPROPRIATIONS, ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 2 (Cal. 2019) ("Specifically, under the bill these types of settlements in pharmaceutical patent infringement cases are presumed to be anticompetitive unless procompetitive effects can be clearly and convincingly demonstrated."), *with* CAL. ASSEMB., ASSEMBLY THIRD READING OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 1 (Cal. 2019) (replacing "clear and convincing" with "a preponderance of the" evidence).

104. *See* HISTORY OF ASSEMBLY BILL NO. 824.

105. S. COMM. ON HEALTH, ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 4 (Cal. 2019) (as amended in Senate, June 17, 2019); Assemb. B. 824 ("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.").

106. Assemb. B. 824.

compensation, and the compensation does not exceed $7.5 million or "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."[107] The second carve-out allows for

> 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.[108]

The Senate further modified these 134002(d) carve-outs in its July 11, 2019 text.[109] Rather than defining these carve-outs as exceptions to the general prohibition created by the bill, the July senate amendment listed these carve-outs as limitations on what the bill construed as "anything of value."[110] This July 11 amendment further clarified who may bring suit, stating that a violation penalty "is recoverable only in a civil action brought by the Attorney General" and that a penalty "shall accrue only to the State of California and shall be recovered in a civil action brought by the Attorney General."[111] The final Senate revision on September 4, 2019, modified what a party must show to succeed on its claim.[112] Previously, a party was required to show that its agreement "directly generated procompetitive benefits *that could not be achieved by less restrictive means*" that "outweigh the anticompetitive effects of the agreement."[113] The "less restrictive means" language was removed, so a party is now only required to

107. *Id.*

108. *Id.*

109. S. JUDICIARY COMM., ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 6 (Cal. 2019) (as amended in Senate, July 11, 2019).

110. *Id.*

111. Assemb. B. 824; *see* S. JUDICIARY COMM., ANALYSIS OF ASSEMBLY BILL NO. 824, at 6.

112. S. RULES COMM., ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 4–5 (Cal. 2019) (as amended in Senate, Sept. 4, 2019).

113. S. JUDICIARY COMM., ANALYSIS OF ASSEMBLY BILL NO. 824, at 4 (as amended in Senate, July 11, 2019) (emphasis added).

show that the agreement "directly generated procompetitive benefits" that "outweigh the anticompetitive effects of the agreement."[114]

The bill was passed as amended in the senate on September 11, referred to the Assembly, and enrolled on September 24, 2019.[115] The bill was approved by the governor on October 7, 2019, and chaptered in Chapter 531.[116]

3. Provisions of AB 824

This legislation empowers the California Attorney General to bring a civil suit and recover penalties against "any party to an agreement that violates this section."[117] It further allows for the presumption of anticompetitive behavior when a "nonreference drug filer" (defined in the bill as an ANDA generic filer or biosimilar manufacturer) "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 "agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time."[118]

Establishing the above creates a presumption of illegal anticompetitive behavior that parties may rebut by showing by a preponderance of the evidence that either: "[t]he value received by the nonreference drug filer . . . is a fair and reasonable compensation solely for other goods or services that the nonreference drug filer has promised to provide" or that the "agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."[119]

While "anything of value" is a broad term, the text carves out six settlement considerations that *do not* constitute something of value for

114. S. RULES COMM., ANALYSIS OF ASSEMBLY BILL NO. 824, at 4 (as amended in Senate, Sept. 4, 2019).

115. CAL. ASSEMB., HISTORY OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess. (Cal. 2019).

116. *Id.*; *see* Act of Oct. 7, 2019, ch. 531, 2019 Cal. Legis. Serv. (West) (to be codified as CAL. HEALTH & SAFETY CODE §§ 13400–134002). Subsequent references to the Act will be to CAL. HEALTH & SAFETY CODE sections.

117. Act of Oct. 7, 2019 § 134002(e)(1)(B) ("Any penalty described in subparagraph (A) shall accrue only to the State of California and 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.").

118. *Id.* § 134002(a)(1)(A)–(B).

119. *Id.* § 134002(a)(3).

the purposes of the bill:[120] First, "the right to market the competing product in the United States before the expiration of either: . . . [a] patent that is the basis for the patent infringement claim" or a "patent right or other statutory exclusivity that would prevent the marketing of the drug."[121] Second, "[a] covenant not to sue on a claim that the nonreference drug product infringes a United States patent."[122] Third, "[c]ompensation for saved reasonable future litigation expenses of the reference drug holder."[123] This compensation must be "reflected in budgets that the reference drug holder documented and adopted at least six months before the settlement" and be less than or equal to the lower of $7.5 million or "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."[124] Fourth, settlements that allow nonreference drug filers (generics and biosimilars) to sell or distribute their nonreference drugs when the reference drug holder (branded company) seeks approval for 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."[125] The bill text, however, notes that authorized generic versions of the reference drug do not constitute a "different form" for the purpose of this subsection.[126] Fifth, a branded drug company's agreements either to facilitate or to not interfere with the "nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product."[127] Finally, settlements in which the branded company "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."[128]

120. *Id.* § 134002(a)(2)(A)–(F).
121. *Id.* § 134002(a)(2)(A).
122. *Id.* § 134002(a)(2)(B).
123. *Id.* § 134002(a)(2)(C).
124. *Id.* This subsection also notes that "[i]f no projections or forecasts are available, the compensation [must] not exceed two hundred fifty thousand dollars ($250,000)."
125. *Id.* § 134002(a)(2)(D).
126. *Id.*
127. *Id.* § 134002(a)(2)(E).
128. *Id.* § 134002(a)(2)(F).

4. Support and Opposition for AB 824

Over the course of its development, key interest groups supported and opposed AB 824. Attorney General Xavier Becerra, at a time when the California Department of Justice emphasized its settlements against pay-for-delay arrangements, supported the bill.[129] There was also general support for the bill among business associations, healthcare advocacy groups, and public interest organizations. Consumer Reports said that "AB 824 will make it easier to stop these [anticompetitive] schemes in their tracks."[130] Small Business Majority supported AB 824, noting that "[c]ontrolling prescription drug prices and ensuring competition, and thus controlling overall healthcare expenses, helps ensure small business owners have access to affordable, quality healthcare options."[131] California Health+ Advocates, a community health center advocacy group, supported AB 824 as a policy that "reduces pharmaceutical costs for patients in California."[132] Health Access, a healthcare consumer advocacy group, said that AB 824 allowed California to prevent the "problematic, price-gouging practice of pay-for-delay by the prescription drug companies."[133] Other groups supporting the bill included AARP California, California Labor Federation, California Public Interest Research Group, Kaiser Permanente, and the Western Center on Law & Poverty, Inc.[134]

The Association for Accessible Medicines, a trade association for generic drug manufacturers, opposed AB 824 because of concerns that it might penalize procompetitive settlements and its belief that *Actavis* represented a sufficient federal framework for antitrust scrutiny.[135]

Other trade associations expressed similar fears and voiced conditional opposition. Biocom, a biotechnology trade association,

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129. Attorney General Becerra Press Release, *supra* note 37.

130. ASSEMB. COMM. ON THE JUDICIARY, ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 14 (Cal. 2019) (hearing Apr. 9, 2019).

131. *Id.*

132. *Id.*

133. Press Release, Health Access, CA Consumers Could Save Millions Under Bills Up in Assembly Health Committee Tuesday (Mar. 25, 2019), https://health-access.org/press_release/2019/03/ca-consumers-could-save-millions-under-bills-up-in-assembly-health-committee-tuesday/.

134. ASSEMB. COMM. ON THE JUDICIARY, ANALYSIS OF ASSEMBLY BILL NO. 824, at 16 (hearing Apr. 9, 2019).

135. *Id.* at 15–16.

was also concerned that the "bill usurps jurisdiction of finding and prosecuting of anti-competitive behavior from the [FTC] and inserts the State of California into this role."[136] Biocom further noted that two provisions—the initial presumption and private right of action—would chill generic entry into the market.[137] The pharmaceutical trade association Pharmaceutical Research and Manufacturers of America likewise sought amendments to: (1) "modify the scope to only include patent infringement claims"; (2) "allow the factfinder to make appropriate determinations based on the circumstances of the case"; and (3) remove the private right of action.[138] These conditions were partially reflected in senate revisions of the bill, which eliminated the private right of action and lowered the requirements that parties must show.[139]

III. ANALYSIS

A. Intent of AB 824

The intent of AB 824 is fairly straightforward. From its title, the law's purpose is to "preserv[e] access to affordable drugs" by prohibiting anticompetitive settlements that raise costs for patients.[140] In a public statement when the bill was introduced, Assembly member Wood said:

> Who loses [as a result of pay-for-delay arrangements]? The patients who deserve access to less expensive drugs and all of us who end up paying more for health care and, in turn, health care premiums. Affordability is a huge issue in health care, and this calculating practice makes it worse and we need to stop it.[141]

136. S. COMM. ON THE JUDICIARY, ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 13 (Cal. 2019) (hearing July 9, 2019).

137. *Id.*

138. CAL. ASSEMB., ASSEMBLY THIRD READING OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 2 (Cal. 2019) (as amended May 16, 2019).

139. S. COMM. ON APPROPRIATIONS, ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 1 (Cal. 2019) (as amended in Senate, July 11, 2019); S. RULES COMM., ANALYSIS OF ASSEMBLY BILL NO. 824, 2019–2020 Reg. Sess., at 2–6 (Cal. 2019) (as amended in Senate, Sept. 4, 2019).

140. Act of Oct. 7, 2019, ch. 531, 2019 Cal. Legis. Serv. (West) (to be codified as CAL. HEALTH & SAFETY CODE §§ 13400–134002).

141. Assemblymember Jim Wood Press Release, *supra* note 100.

Attorney General Becerra added that "[t]his legislation is a crucial step in combating predatory pricing practices, like 'pay-for-delay' schemes, by drug companies and in defending access to affordable care."[142]

B. Efficacy of AB 824

The intent of the legislation is relatively clear. The larger question is whether AB 824 can achieve its goals of lowering pharmaceutical costs and preserving affordable drugs for patients. This efficacy analysis requires examining: (1) the expansion and limitations placed on antitrust enforcement by the law's text and amendments; (2) the ability of the law to prohibit the variety of anticompetitive settlements; (3) whether the law might survive a nascent challenge; and (4) whether AB 824 is an effective mechanism for addressing high drug costs for patients.

1. Expansion and Limits of Antitrust Enforcement Created by AB 824

The main expansion of AB 824 is clear. It shifts the burden from enforcers to the branded and generic companies, requiring them to prove that their settlement is not anticompetitive. Practically, this lowers the barrier to what the Attorney General must prove to obtain penalties against such anticompetitive behavior. Rather than requiring the Attorney General to build large cases showing collusion between companies, the burden now falls on branded and generic drug companies to show that their behavior is not harmful. Furthermore, AB 824 makes it more difficult for judges to approve pay-for-delay arrangements. As antitrust practitioners have noted, some judges have been "erod[ing]" enforcement of federal antitrust laws since the 1970s.[143] While judges may still rule in favor of an anticompetitive pay-for-delay arrangement, this legislation creates additional hurdles.

However, this law is not a blunt prohibition on all settlements between branded and generic drug manufacturers. It places key limitations on actions against these parties. Only the California

142. *Id.*

143. John Newman, *What Democratic Contenders Are Missing in the Race to Revive Antitrust*, THE ATLANTIC (Apr. 1, 2019), https://www.theatlantic.com/ideas/archive/2019/04/what-2020-democratic-candidates-miss-about-antitrust/586135/.

Attorney General—not private parties or the United States Department of Justice or FTC—may seek remedies under this law.[144] Additionally, although it shifts the burden, it allows for numerous exceptions. It limits "anything of value" to exclude certain scenarios involving agreements related to: the right to market, covenants to not sue, compensation for branded company's future litigation expenses, the branded company's new form or dosage of the reference drug, regulatory approval for the generic drug, and forgiveness of potential damages.[145]

The bill also allows companies to prove by a preponderance of the evidence that the settlement either offers procompetitive benefits that outweigh the anticompetitive harms or is "fair and reasonable compensation solely for other goods or services that the nonreference drug filer has promised to provide."[146] While branded and generic drug companies were concerned that it would prevent procompetitive settlements, the exceptions to "anything of value" and ways to disprove liability show that this legislation is not overly broad.

2. AB 824's Ability to Capture Increasingly Complex Pay-For-Delay Settlements

While not being overly broad, AB 824 raises the question of whether—with all of its carveouts—it can still prohibit the intended anticompetitive pay-for-delay schemes. While the FTC in 2016 celebrated a decline in traditional compensation pay-for-delay arrangements post-*Actavis*, they have also reported settlements where the arrangements present potential compensation.[147] Beyond the FTC's detection of such potential pay-for-delay settlements, scholars

144. Act of Oct. 7, 2019 § 134002(e)(1)(B) ("Any penalty described in subparagraph (A) shall accrue only to the State of California and 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.").

145. *Id.* § 134002(a)(2).

146. *Id.* § 134002(a)(3)(A).

147. Feldman & Misra, *supra* note 4, at 249, 261–62 ("FTC reports and commentary suggest that the agency may have 'finally started to turn the corner on the issue.' In a [2016] FTC blog, for example, the FTC concluded that although more settlements between brand-name companies and generics occurred than in any previous year, pharmaceutical companies managed to settle without "any compensation" to the generic company 80 percent of the time."); Jamie Towey & Brad Albert, *Is* FTC v. Actavis *Causing Pharma Companies to Change Their Behavior?*, FED. TRADE COMM'N (Jan. 13, 2016, 1:00 PM), https://www.ftc.gov/news-events/blogs/competition-matters/2016/01/ftc-v-actavis-causing-pharma-companies-change-their.

have also noted that 74 percent of settlements between branded and generic parties in 2015 delayed generic entry but exchanged no discernible value.[148] This raises the specter that branded and generic drug companies are simply creating more complex pay-for-delay arrangements.

AB 824 only prohibits the exchange of "anything of value" and excludes several considerations from being considered something of value.[149] Some of these exclusions, including considerations of noninterference with regulatory approval and the branded drug company's forgiveness of potential damages, which were added in the senate following drug company requests, could provide vehicles for key exchanges that are now deemed not of value.[150]

The focus on the exchange itself rather than the resulting restrictions on entry is understandable given courts' concern about whether these settlements represent parties' fair estimations of patent value or a monopolistic toll. However, as scholars surveying the pay-for-delay landscape have suggested, this analysis does not account for settlement items such as acceleration clauses that still present anticompetitive harms.[151] Some scholars have suggested that a better framework would be to examine the "existence of a restriction on generic entry . . . in light of the strength of the category of patent in question."[152] Using a different methodology, Professor Michael Carrier offered a test that analyzes "whether the brand has conveyed to the generic a type of consideration not available as a direct consequence of winning the lawsuit."[153] These restriction-based and consideration-based approaches cast a wider net for anticompetitive arrangements while preserving parties' ability to settle. AB 824's focus on payments, instead, may prove insufficient to capture the different harms to competition posed by these settlements.

These limitations lessen the legislation's efficacy in scrutinizing an industry that has already made adjustments to their quid pro quo arrangements. Furthermore, given the decade it took to pass any pay-for-delay legislation, it is unlikely that legislators would pass new bills adapting to new forms of pay-for-delay arrangements. The danger of

148. Feldman & Misra, *supra* note 4, at 264.
149. Act of Oct. 7, 2019 § 134002(a)(1)–(2).
150. *Id.* § 134002(a)(2).
151. Karas et al., *supra* note 80, at 965; Carrier, *supra* note 82, at 40–41.
152. Karas et al., *supra* note 80, at 968.
153. Carrier, *supra* note 82, at 26.

pay-for-delay mutations means that this more static legislation could calcify into only creating liability for traditional pay-for-delay models that most branded and generic companies would avoid.

Although loopholes remain an issue, AB 824 still has the potential to limit pay-for-delay costs on consumers. The burden shift to companies from a more lenient rule of reason standard is a significant step forward. While *Actavis* reopened the door for antitrust scrutiny, agencies still need to satisfy a rule of reason analysis that is "complex and burdensome on litigants and the judicial system."[154] AB 824 instead simply requires antitrust enforcers to show the exchange of something of value between branded drug companies and generic manufacturers and the delayed entry of the generic drug. This relieves agencies of expending significant resources on what should be straightforward cases and allows for a cleaner analysis for courts that misunderstand anticompetitive harms.

In addition, the pharmaceutical industry's challenge of the bill suggests that it has a role to play in prohibiting pay-for-delay agreements. Following the passage of AB 824, the general counsel for Association for Accessible Medicines (AAM), a generic drug trade association, said that "most settlements have a provision that would trigger anticompetitive presumption" and referenced an "acceleration clause whereby if another generic manufacturer launches its product, the party to the settlement can market its generic at the same time."[155] Despite the fact that AB 824 allows companies to dispute the presumption, AAM worried that this would "trigger the 'anything of value' provision" and create an anticompetitive presumption.[156] The industry's concern about the legislation's potential application to many settlements suggests that it may be effective in discouraging anticompetitive pay-for-delay arrangements.

Finally, this legislation allows for scrutiny of generic versions of small-molecule branded drugs and large-molecule biologic drugs. Biologic drugs and their biosimilar generic versions represent a growing percentage of the pharmaceutical industry.[157] This legislation's decision to use "nonreference drug filer," "nonreference drug product," "reference drug holder," and "reference drug product"

154. Feldman, *supra* note 3, at 2107.
155. Sandburg, *supra* note 93.
156. *Id.*
157. Feldman & Misra, *supra* note 4, at 266–67.

rather than the simpler "generic" and "brand" distinction reflects the same recognition that the federal Preserve Access to Affordable Generics and Biosimilars Act made—biosimilars and biologics are subject to the same incentives as ANDA and branded small molecule drugs.[158] This inclusion allows the Attorney General to police this growing marketplace in the same fashion as the traditional small molecule market.

3. Dormant Commerce Clause Challenge

In November 2019, the AAM filed suit in the Eastern District of California against Attorney General Becerra to block enforcement of this legislation.[159] It primarily alleges federal constitutional claims: a dormant commerce clause claim, a preemption claim, and an excessive fine Eighth Amendment claim.[160] Examining AAM's claim is useful in both understanding challenges to this specific legislation and for highlighting potential tension between state antitrust legislation and federalist principles.

In its dormant commerce clause claim, AAM alleges that the legislation violates the clause because it contains no geographic limitations on the patent settlements to which it applies.[161] Citing *Healy v. Beer Institute*,[162] AAM suggests that when a state law in effect regulates "commerce occurring wholly outside [the] State's borders," it will be "struck down under the Commerce Clause 'whether or not the regulated commerce has effects within the state.'"[163] While noting that "AB 824 does not expressly refer to out-of-state commerce," AAM states that the Supreme Court has held that the fact that state legislation "is addressed only to" conduct "in [the

158. Act of Oct. 7, 2019, ch. 531, § 134000, 2019 Cal. Legis. Serv. (West); S.3792, 115th Cong. (2018).

159. *See* Complaint at 1, Ass'n for Accessible Meds. v. Becerra, No. 2:19-cv-02281-TLN-DB (E.D. Cal. Nov. 12, 2019) [hereinafter AAM Complaint].

160. *Id.* at 30–46.

161. *Id.* at 31–32 ("AB 824 extends to commerce (namely, patent settlements) negotiated, signed, and entered wholly outside the borders of California. AB 824 contains no restrictions that would limit its application to settlement agreements between California entities, and no restrictions that would limit its application to settlement agreements that were negotiated, completed, or entered in California.").

162. 491 U.S. 324 (1989).

163. *See* AAM Complaint, *supra* note 159, at 31 (alteration in original) (emphasis omitted) (quoting *Healy*, 491 U.S. at 335–36).

state] is irrelevant if the 'practical effect'" is to regulate conduct "in other States."[164]

However, dormant commerce clause based reviews of state legislation affecting external transactions have been more lenient than AAM's discussion suggests. Dormant commerce clause reviews of state statutes frequently apply the flexible *Pike v. Bruce Church, Inc.*[165] balancing test that states, "[w]here the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."[166] Other courts have formulated the test as requiring the examination of:

> (1) whether the challenged statute regulates evenhandedly with only "incidental" effects on interstate commerce, or discriminates against interstate commerce either on its face or in practical effect;
>
> (2) whether the statute serves a legitimate local purpose; and, if so,
>
> (3) whether alternative means could promote this local purpose as well without discriminating against interstate commerce.[167]

A key element of the *Pike* test is the "evenhandedness" with which the statute regulates. Some courts have held that if a statute affects both in-state and out-of-state transactions relatively equally, the dormant commerce clause is likely not implicated, and it is unnecessary to even apply the *Pike* test.[168] In the case of AB 824, there is no disparity between the legislation's treatment of in-state and out-of-state actors. The legislation's text does not single out California pharmaceutical firms or out-of-state pharmaceutical firms in terms of

164. *Id.* at 32 (alteration in original) (emphasis omitted) (quoting Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986)).

165. 397 U.S. 137 (1970).

166. *Id.* at 142.

167. Hughes v. Oklahoma, 441 U.S. 322, 336 (1979) (citing *Pike*, 397 U.S. at 142).

168. Chinatown Neighborhood Ass'n v. Harris, 33 F. Supp. 3d 1085, 1101 (N.D. Cal. 2014), *aff'd*, 794 F.3d 1136 (9th Cir. 2015) ("[W]here, as here, there is no discrimination and there is no significant burden on interstate commerce, we need not examine the actual or putative benefits of the challenged statutes." (quoting Nat'l Ass'n of Optometrists & Opticians v. Harris, 682 F.3d 1144, 1155 (2012))).

enforcement.[169] Nor does it include exceptions that only apply to in-state firms.[170] While enforcement actions may reveal the legislation's disparate impact on in-state and out-of-state firms, at present the statute appears to apply evenhandedly towards both designations.

Even applying the *Pike* test, it still provides a fairly lenient standard. A court must find that "the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."[171] The Ninth Circuit has taken this to mean that "[f]or a facially neutral statute to violate the commerce clause, the burdens of the statute must so outweigh the putative benefits as to make the statute unreasonable or irrational."[172] "Such is the case," the court noted, "where the asserted benefits of the statute are in fact illusory or relate to goals that evidence an impermissible favoritism of in-state industry over out-of-state industry."[173] In examining a city ordinance that required contractors to provide benefits to employees with registered domestic partners, the Ninth Circuit noted that "[w]hile we do not require a dollar estimate of the effect the Ordinance will have, we do require specific details as to how the costs of the Ordinance burdened interstate commerce."[174] It further clarified that "[t]he Commerce Clause is concerned with the free flow of goods and services through the several states; it is the *economic* interest in being free from trade barriers that the clause protects."[175] This suggests that the Ninth Circuit believes the primary function of the dormant commerce clause to be preventing state-against-state protectionism and trade barriers, not to necessarily prohibit states from regulating all transactions that have an effect on their citizens but involve some out-of-state elements.

AAM alternately suggests a broader dormant commerce clause basis for striking down state laws that affect out-of-state firms. It cites *Healy* as holding that the Court will strike down state laws regulating "commerce occurring wholly outside [the] State's borders," regardless

169. *See* Act of Oct. 7, 2019, ch. 531, 2019 Cal. Legis. Serv. (West) (omitting explicit references to California-based firms or externally-based firms).

170. *See id.* (omitting language that restricts application to California firms exclusively).

171. *Pike*, 397 U.S. at 142 (citing Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 443 (1960)).

172. Alaska Airlines, Inc. v. City of Long Beach, 951 F.2d 977, 983 (9th Cir. 1991).

173. *Id.*

174. S.D. Myers, Inc. v. City and Cnty. of S.F., 253 F.3d 461, 471 (9th Cir. 2001).

175. *Id.*

of whether the regulated commerce has in-state effects.[176] AAM also cites *Brown-Forman Distillers Corp. v. New York State Liquor Authority*[177] as holding that legislation's direction at intrastate commerce is irrelevant if the "practical effect" of the legislation is to regulate external commerce.[178]

However, other courts have found *Healy* and *Brown-Forman Distillers* to be narrower than AAM's hoped-for rule. The Tenth Circuit noted that in these cases, "the Court . . . faced (1) a price control or price affirmation regulation, (2) linking in-state prices to those charged elsewhere, with (3) the effect of raising costs for out-of-state consumers or rival businesses."[179] The Court itself appears to emphasize the central dormant commerce clause rule in *Healy*: "States may not deprive businesses and consumers in other States of 'whatever competitive advantages they may possess' based on the conditions of the local market."[180]

In sum, the principal purpose of the dormant commerce clause appears to be preventing protectionism between the states; review of a potential dormant commerce clause frequently involves the fairly lenient *Pike* balancing test that favors upholding state laws; and courts' analyses tend to focus on whether states are erecting trade barriers to favor their own industries. While the *Pike* test does allow for court discretion in balancing the factors, the lack of protectionist tendencies in this legislation suggests it is unlikely to implicate the dormant commerce clause.

4. Preemption Challenge

In its preemption claim, AAM argues that the barriers to settlement imposed by AB 824 undermine "not only the rights that federal patent law confers, but also the timely entry of lower-priced generic medicines onto the market."[181] Generally, the Supreme Court has found conflict preemption occurs "where 'compliance with both state and federal law is impossible,' or where 'the state law "stands as

176. AAM Complaint, *supra* note 159, at 31 (alteration in original) (quoting Healy v. Beer Inst., 492 U.S. 324, 332 (1989)).

177. 476 U.S. 573 (1986).

178. AAM Complaint, *supra* note 159, at 31 (quoting *Healy*, 492 U.S. at 336).

179. Energy & Env't Legal Inst. v. Epel, 793 F.3d 1169, 1173 (10th Cir. 2015).

180. *Healy*, 492 U.S. at 339 (quoting *Brown-Forman Distillers*, 476 U.S. at 580).

181. AAM Complaint, *supra* note 159, at 41.

an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"'"[182] A cursory look might thus suggest this legislation would be preempted. This legislation attempts to curb the pay-for-delay results of the Hatch-Waxman's ANDA process. It interacts with patents that branded drug companies own. And scholars have suggested that similar state patent legislation—statutes that prohibit patent trolling—may indeed be preempted.[183] Upon closer inspection, however, AB 824 does not impede the underlying goals of patent laws or the Hatch-Waxman Act.[184]

In *Wyeth v. Levine*,[185] the Court outlined the "two cornerstones of our pre-emption jurisprudence."[186] "First, 'the purpose of Congress is the ultimate touchstone in every pre-emption case.'"[187] "Second, '[i]n all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," . . . we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."'"[188]

The congressional purpose underlying the Hatch-Waxman Act was to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962."[189] Representative Henry Waxman, one of its drafters, described it as "an early attempt to address the problem of prescription drug prices by encouraging competition against brand-name drugs from generic drug manufacturers."[190] Its ANDA process is merely a means to the ends, not the ends in itself. In an amicus brief clarifying the policy behind Hatch-Waxman, Representative Waxman

182. Oneok, Inc. v. Learjet, Inc., 575 U.S. 373, 377 (2015) (quoting California v. ARC Am. Corp., 490 U.S. 93, 100–01 (1989)).

183. Paul R. Gugliuzza, *Patent Trolls and Preemption*, 101 VA. L. REV. 1579, 1583 (2015).

184. This analysis was aided by the amicus brief filed by Professor Michael Carrier in the case's Ninth Circuit appeal. *See generally* Brief Amicus Curiae in Support of Appellee's Answering Brief, Ass'n for Accessible Meds. v. Becerra, No. 20-15014, 2020 WL 4251776 (9th Cir. July 24, 2020) [hereinafter Professor Michael Carrier Amicus Curiae Brief].

185. 555 U.S. 555 (2009).

186. *Id.* at 565.

187. *Id.* (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

188. *Id.* (quoting *Medtronic*, 518 U.S. at 485).

189. H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

190. Motion and Brief of Representative Henry A. Waxman as Amicus Curiae in Support of Petitioner at 3, Fed. Trade Comm'n v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2462026, at *3.

commented that "[a]greeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote genetic alternatives."[191] He further noted that, "[b]y subjecting [pay-for-delay settlements] to stringent governmental scrutiny and providing an additional penalty if they were found to violate the antitrust laws, the 2003 [Medicare Drug Benefit Legislation] underscored that the Hatch-Waxman Act was never intended to foster such anti-competitive arrangements."[192]

Like the Hatch-Waxman Act's goal of ensuring low-cost generic availability, AB 824 aims to make necessary drugs affordable to California patients. In method, it similarly leverages market competition to drive down drug prices. As AB 824 does not diverge from the objectives laid out by Hatch-Waxman's drafters and instead attempts to ameliorate the anticompetitive side effects of the ANDA process, its purpose mirrors Congress's purpose. Given the primacy of congressional intent in preemption analysis, it is therefore not likely to be preempted by the Hatch-Waxman Act.

In examining the potential preemption of AB 824 by federal patent law, Professor Michael Carrier emphasizes that the Court has rejected the "absolutist" approach that prohibits antitrust scrutiny of patent disputes.[193] In *Actavis*, the Court noted that a patent's exclusionary potential does not "immunize the agreement from antitrust attack."[194] Looking at precedent, the Court found that "patent-related settlement agreements can sometimes violate the antitrust laws."[195] The Court also noted the variety of outcomes in patent disputes—patent holders are only permitted to enforce their monopoly when their patent is found to be valid and infringed.[196] Instead of following the Eleventh Circuit's immunization of companies based on one party's assertion that its patent was valid and infringed, the Court found that "a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes

191. *Id.* at *7.
192. *Id.* at *10.
193. Professor Michael Carrier Amicus Curiae Brief, *supra* note 184, at 15.
194. Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 147 (2013).
195. *Id.* at 149.
196. *Id.* at 147.

without the use of reverse payments."[197] Accordingly, the Court opposed determining "antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."[198] By ensuring that judges take into account antitrust concerns rather than rubberstamping patent settlements as was done pre-*Actavis*, AB 824 codifies the *Actavis* recognition that antitrust scrutiny can coexist with patent protections.

Returning to the legislative intent underlying patent law, courts have noted that "the fundamental purpose of patent law is to promote innovation and the disclosure of inventions so that ultimately new discoveries may benefit the public at large."[199] AB 824 does not interfere with this goal of promoting innovation. Its language includes numerous carveouts to ensure that competitive settlements are not unfairly affected while ensuring that settlements that would harm the public are subject to scrutiny. Because this legislation does not depart from patent law's innovation intent and because the Supreme Court has explicitly recognized the necessity of antitrust scrutiny coexisting with patent settlements, AB 824 does not appear to be preempted by federal patent law.

5. AB 824's Role in Lowering Drug Prices—Survey of Complementary Solutions

Finally, in assessing whether this legislation will impact high drug pricing, it is important to examine the overall pharmaceutical landscape. Some calculations have suggested that savings from a ban on pay-for-delay arrangements could save consumers approximately $3.5 billion per year.[200] Others have found "a transfer from consumers to producers" of approximately $12 to $14 billion per year's delay of generic entry.[201] The total U.S. expenditure on pharmaceuticals for 2016, however, was estimated to be approximately $480 billion.[202] Of

197. *Id.* at 158.

198. *Id.* at 148.

199. *In re* Cipro Cases I & II, 348 P.3d 845, 857 (Cal. 2015) (citing Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989)).

200. Leibowitz Speech, *supra* note 25, at 1.

201. Hemphill, *An Aggregate Approach to Antitrust*, *supra* note 22, at 650.

202. Nancy L. Yu et al., *Spending on Prescription Drugs in the US: Where Does All the Money Go?*, HEALTH AFFS.: BLOG (July 31, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180726.670593/full.

this $480 billion, $323 billion (two-thirds of the total amount) went to drug manufacturers, while the other third went to the supply chain.[203] AB 824 targets a key portion of these expenditures—the drug manufacturers—by preventing anticompetitive agreements between them. There are still potential inefficiencies from both the manufacturers and supply chain sectors that other policies could reduce or eliminate.

Some state legislatures have introduced bills that more directly set limits on drug pricing.[204] Some of these bills, such as Maryland's, impose a burden on drug manufacturers to explain certain price increases—Maryland suggests a 50 percent increase figure as a potential violation in the bill's text—or pay a fine.[205] Others, like New York's, require drug manufacturers to reimburse the state if their drug prices exceed price targets set by the Department of Health.[206] These bills benefit from directly setting limits and controls on prices. However, some have noted that their scope remains limited—Maryland's law solely deals with generic drugs while New York's is limited to Medicaid payments.[207] Other state pricing bills have taken a more comprehensive approach, but these bills have not progressed past committee.[208]

Other methods to bring down costs have also been proposed. Some have suggested implementing final-offer arbitration between drug manufacturers and drug purchasers (such as pharmacy benefit managers) to force a more reasonable solution for drug pricing disputes.[209] Others have proposed modeling or modifying price gouging laws meant to curb gouging in times of crisis to include pharmaceutical products.[210] More dramatic approaches—such as

203. *Id.*

204. *See* Primer, Curbing Unfair Drug Prices: A Primer for States, from Aaron Berman et al. 6, 18–19 (Aug. 2017) [hereinafter Aaron Berman Primer] (identifying in the appendix thirteen states and the District of Columbia that have proposed or enacted direct pricing bills).

205. *Id.* at 6; H.B. 631, 2017 Gen. Assemb., Reg. Sess. § 2-803(A) (Md. 2017).

206. *See* Aaron Berman Primer, *supra* note 204, at 6; S. 2007B, 2017–2018 Reg. Sess., at 4–13 (N.Y. 2017).

207. *See* Aaron Berman Primer, *supra* note 204, at 6.

208. *Id.*; *see, e.g.*, S.627, 190th Gen. Ct., Reg. Sess. (Mass. 2017); S.793, 79th Or. Legis. Assemb., Reg. Sess. (Or. 2017).

209. Eric Lamm, Comment, *Keeping Consumers Out of the Crossfire: Final-Offer Arbitration in the Pharmaceutical Market*, 65 UCLA L. REV. 926, 957–58 (2018).

210. Michelle M. Mello & Rebecca E. Wolitz, *Legal Strategies for Reining in "Unconscionable" Prices for Prescription Drugs*, 114 NW. U. L. REV. 859, 897–905 (2020).

nationalizing the pharmaceutical industry through the creation of a medicines agency—have also been proposed.[211]

Given the multitude of factors that drive drug prices, some states have also introduced bills requiring drug manufacturers to publicly report major cost data.[212] These bills would allow the public to more easily understand when drug manufacturers are engaging in price gouging by revealing different factors such as costs associated with research and development, manufacturing, marketing, advertising, and regulatory approval.[213] Supported by this information, the public could then demand further action by regulators, legislators, and the companies to lower exorbitant prices.[214] Not all of the state bills, however, require comprehensive disclosure of the different factors, and not all bills apply to every marketed drug.[215] These limitations could prevent the public and legislators from becoming fully informed, which might hinder the push for further drug price reform. In addition, this puts the burden on the public to constantly monitor and push for further legislative or regulatory action, rather than legislators simply imposing price caps.

At an agency level, federal antitrust enforcers could undertake further actions against anticompetitive scenarios in various sectors of the pharmaceutical industry. For instance, in addition to collusive agreements between drug manufacturers themselves, there is intense concentration in the principal agents for pharmaceutical purchasers. One report estimated that within the pharmaceutical benefit manager sector, 70–75 percent of all prescription claims are handled by the top three companies.[216] In the pharmaceutical wholesaler industry, the top

211. Fran Quigley, *Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry*, U. MICH. J.L. REFORM (forthcoming).

212. *See* Aaron Berman Primer, *supra* note 204, at 7, 15–17 (identifying in the appendix fourteen states that have proposed drug cost transparency bills).

213. *Id.* at 7.

214. *Id.*

215. *See id.* at 7–8 (noting that "[m]ost bills exist on a spectrum" between transparency mandates, which call for public disclosure of specified information, and reporting mandates, which require reports to be provided only to regulators).

216. Yu et al., *supra* note 202 ("Within the PBM industry, approximately 70–75 percent of all prescription claims are handled by the top three companies: Express Scripts, CVS Caremark, and OptumRx. The first two, which account for more than half of the industry's prescription drug claims, disclose gross profits for their PBM/pharmacy services business. United Healthcare reports OptumRx's revenues, to which we applied a 5 percent margin (comparable to CVS Caremark's) to estimate its gross profits, bringing total profits for the 'big three' to a little more than $17 billion.").

three wholesalers receive 85–90 percent of drug distribution revenues, with the top two wholesalers together receiving over 60 percent of revenues.[217] If antitrust agencies are interested in spurring different firms to compete on pricing, bringing actions to decrease the concentration of different sectors within the pharmaceutical market could be beneficial. This could run into judicial hurdles, but it presents a further opportunity to leverage the antitrust laws in favor of lowering drug costs.[218]

Assuming no nationalization or national price caps, each solution by itself is insufficiently comprehensive to bring about reasonable drug prices. However, all offer a partial fix. AB 824 thus might represent one part of a larger tapestry of price-decreasing solutions. Although it remains a limited solution, AB 824 targets a clear inefficiency within the system—agreements that prevent price-lowering competition between drug manufacturers—and attempts to eliminate that efficiency.

IV. CONCLUSION

Scholars have recognized the toll pay-for-delay arrangements take on consumers for the last fifteen years.[219] Despite the understanding of this problem, the rule of reason approach taken by federal courts still places a heavy burden on enforcers. Federal legislation to shift the burden to companies has stalled, and no other states have passed legislation on this issue.

Given the need for agencies to address these issues, California's recent law presents a step forward. While stopping short of per se illegality, shifting the burden to drug manufacturers will make it easier to prevent anticompetitive pay-for-delays arrangements. The legislation's focus on value and numerous exceptions may undermine its ability to capture increasingly complex pay-for-delay manifestations in which an exchange of value is difficult to detect. However, its application to every transaction where there is an exchange of value is a significant improvement to the prior rule of reason analysis.

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217. *Id.*

218. *See* Newman, *supra* note 143 (arguing that proponents of antitrust reform must not ignore the role of federal judges in antitrust enforcement).

219. Hemphill, *Paying for Delay*, *supra* note 13, at 1557.

While this legislation represents only one piece of the solution to high drug prices, there is no panacea for drug pricing problems short of a comprehensive, widely applied cap on drug prices. Accordingly, California's pay-for-delay legislation could work in tandem with other policy proposals—such as certain price caps, greater transparency requirements, negotiations—to target the inefficiencies in the pharmaceutical industry and help reduce drug costs.