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The US Congress introduces a package of bills seeking changes to antitrust and patent law in the pharmaceutical industry

REGULATORY, PHARMACEUTICAL, REFORM, UNITED STATES OF AMERICA, STANDARD ESSENTIAL PATENT, COMPETITION POLICY

US Congress, *Preserve Access to Affordable Generics and Biosimilars Act*, S.64, 29 April 2021

US Congress, *Affordable Prescriptions for Patients Through Promoting Competition Act of 2019*, H.R.4398, 29 April 2021

US Congress, *Stop STALLING Act*, H.R.2374, 29 April 2021

US Congress, *Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019*, H.R.3991, 29 April 2021

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The pharmaceutical industry, like the technology sector, has become as a focus of U.S. lawmakers seeking to revise competition law. In April 2021, House and Senate lawmakers introduced a package of legislation targeting conduct that supposedly prevents or slows competition from less expensive drugs.

Three bills propose antitrust changes targeting so-called "reverse payment" patent settlements, "product hopping," and "sham" citizen petitioning. The presumptions created by these bills would increase the risk associated with licensing and other business arrangements between parties settling patent cases, as well as with launching newer versions of existing drugs and petitioning the FDA.

The fourth bill caps the number of patents in an infringement action resulting from the "patent dance" information exchange in the abbreviated approval pathway for biosimilars.

On April 29, 2021, the House Judiciary Antitrust Subcommittee held a hearing that kick-started a discussion on changes to existing antitrust and patent laws to address prescription drug pricing. House and Senate lawmakers used the hearing to introduce a legislative package of four previously introduced bills that would rewrite antitrust and patent enforcement in the pharmaceutical industry.

- **The Preserve Access to Affordable Generics and Biosimilars Act ("S. 64")**, introduced by Representatives Carolyn Maloney (D-NY), Jerry Nadler (D-NY), and Ken Buck (R-CO) alongside Senators Amy Klobuchar (D-MI) and Chuck Grassley (R-IA), would amend the Federal Trade Commission Act ("FTC Act") to make so-called "reverse-payment" (or "pay-for-delay") settlements presumptively illegal [1].
- **The Affordable Prescriptions for Patients through Promoting Competition Act ("H.R. 4398")**, introduced by Representatives Maloney, Buck, and David Cicicilline (D-RI) as well as Senators Richard Blumenthal (D-CT) and John Cornyn (R-TX), would amend the FTC Act to prohibit certain so-called "hard" and "soft" switch "product hopping" [2].
- **The Stop STALLING Act ("H.R. 2374")**, proposed by Representatives Hakeem Jeffries (D-NY), Buck, and Maloney and Senators Klobuchar and Grassley, would penalize brand drug makers for what the bill describe as "sham" citizen petitions to delay generic and biosimilar competitors [3].
- **The Affordable Prescriptions for Patients through Improvements to Patent Litigation Act ("H.R. 3991")**, proposed by Representatives Henry C. Johnson (D-GA) and Darrell Issa (R-CA) and Senators Blumenthal and Cornyn, would limit the number of patents brand biologic drug makers can assert in an infringement action against a biosimilar following the "patent dance" [4].

The introduction of this targeted legislative package indicates that federal lawmakers are refocusing their attention on drug pricing. In the few weeks since the April 29, 2021 House Judiciary Antitrust Subcommittee hearing, additional House subcommittees have held hearings to push separate initiatives on drug prices, such as reinvigorating H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, introduced in December 2019 to empower Medicare to negotiate drug prices and make those prices available to commercial plans [5].

Below we provide a short summary of each of the four proposed bills, as well as key takeaways.

Preserve Access to Affordable Generics and Biosimilars Act ("S. 64")

The Preserve Access to Affordable Generics and Biosimilars Act would change the law established by the U.S. Supreme Court in **Actavis** for evaluating "reverse payment" patent settlements. In **Actavis**, the Supreme Court rejected the application of a per se or "quick look" analysis of supposed "reverse payment" patent settlement agreements in favor of a traditional antitrust rule of reason analysis [6]. That is, under **Actavis**, a plaintiff needs to prove that the patent settlement included a "large" and "unexplained" payment to the alleged infringer that created an anticompetitive effect before the burden shifts to the defendant to offer its procompetitive justifications [7]. This bill, however, would override the **Actavis** framework by creating a legal presumption of anticompetitive effect, and thus an antitrust violation, if the patent challenger "receives anything of value" as part of the settlement [8]. Key takeaways include:

- **Presumption of Anticompetitive Effects and Violation:** The bill amends the FTC Act to create a legal presumption that a patent settlement has "anticompetitive effects and shall violate" the FTC Act if the alleged infringer receives "anything of value, including an exclusive license," in exchange for limiting or foregoing R&D, manufacturing, marketing or sales of the allegedly infringing product "for any period of time" [9]. This presumption applies to final or interim settlements or resolutions of patent infringement claims involving generic or biosimilar products [10].
- **Limited Pathway to Rebut the Presumption:** The bill increases the evidentiary burden for the parties to

rebut the presumption of illegality and limits what courts may consider in evaluating procompetitive benefits of the conduct. The presumption applies unless the parties prove by clear and convincing evidence that either (1) the "value" provided to the generic is compensation "solely for other goods and services" that the alleged infringer "has promised to provide," or (2) the settlement's procompetitive benefits outweigh its anticompetitive effects [11]. The bill further tilts against the parties by barring the fact finder from presuming that market entry would not have occurred until the relevant exclusivity expired [12]. The fact finder also is barred from presuming that early entry allowed by the settlement agreement (i.e., competitive entry prior to the end of exclusivity) means that the agreement is pro-competitive [13].

- **Narrow Safe Harbor for Early Entry / Litigation Cost Payments up to \$7.5 Million:** The bill includes a safe harbor for settlement provisions that provide for early entry or payment of "reasonable litigation expenses" to the alleged infringer of no more than US\$7.5M [14].
- **Civil Penalties - New Treble Damages Government Penalty:** A violation is treated as a violation of Section 5 of the FTC Act and subject to civil penalties up to three times the value received by the violator that is reasonably attributable to the violation, in addition to mandatory injunctions or other equitable relief as the district court deems appropriate [15]. In the absence of any such value to the innovator, penalties for the innovator may be as much as three times the value given to the alleged infringer [16]. Additionally, a violation would result in a forfeiture of the generic's 180-day Hatch-Waxman exclusivity period [17].
- **Certification of Settlement Agreements by CEOs:** The bill adds to the patent settlement filing requirements of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") [18]. The MMA requires brand, generic, and biosimilar manufacturers to file specified patent settlement agreements with the FTC and Department of Justice [19]. The bill adds a certification requirement directing the Chief Executive Officer or another company official responsible for negotiating the settlement agreement to certify that the materials submitted to fulfill the filing requirement are true, complete, and correct and represent the full agreement between the parties [20].
- **Similar to A.B. 824, California's 2019 Reverse Payment Law:** This bill echoes the California legislation enacted on October 7, 2019, Assembly Bill 824 ("AB 824"), that renders certain pharmaceutical patent litigation settlement agreements presumptively anticompetitive [21]. The similarities between this bill and A.B. 824 include standards for applying anticompetitive presumptions [22], shifting the burden to defendants to rebut that presumption, the narrow safe harbor for payment of reasonable litigation expenses [23], and the amount of penalties [24]. On the other hand, while this bill is silent on market definition, A.B. 824 went one step further to create the presumption that the relevant product market includes only the brand drug and its generic or biosimilar counterparts [25].

Affordable Prescriptions for Patients through Promoting Competition Act ("H.R. 4398")

The Affordable Prescriptions for Patients through Promoting Competition Act would amend the FTC Act to target so-called "product hopping," creating an unfair method of competition violation under Section 5(a) for both "hard" switches, where a new product introduction is followed by the discontinuation of an older version, as well as "soft" switches, where the old version of the product is left on the market. Key takeaways include:

- **Prima Facie Unfair Competition Violation:** The bill amends the FTC Act to create a prima facie case of unfair competition in violation of Section 5 upon a showing by the FTC that the innovator manufacturer engaged

in either a "hard" or "soft" switch from a listed or reference product to a follow-on product. Actions that constitute a prohibited "hard" switch include (i) delisting or discontinuing the listed or reference product's approval with the FDA; (ii) announcing the discontinuation (or intent to discontinue) the listed or reference drug "in a manner that impedes competition from" a generic or biosimilar version and selling a follow-on version of that product; or (iii) destroying the inventory of a listed or reference drug "in a manner that impedes competition" from a generic or biosimilar version [26]. A prohibited "soft" switch would occur if a manufacturer "unfairly disadvantages"—a term the bill does not define—its listed or reference drug "relative to" its follow-on version "in a manner that impedes competition" from a generic or biosimilar version [27]. In either "switch" scenario, the bill would make the "switch" unlawful if it occurs within a window of time beginning with the first notice to the innovator of a generic or biosimilar filing for regulatory approval with the FDA and ending 180 days after the generic is first marketed [28]. The bill defines a "follow-on" product broadly as a drug or biologic approved through a regulatory application or supplement that includes a "change, modification, or reformulation to the same manufacturer's previously approved drug or biological product that treats the same medical condition," but excludes a change, modification, or reformulation that is requested by the FDA or necessary to comply with law [29].

- **Burden on Manufacturer to "Justify" Product Decisions:** The bill defines only three "justifications" that allow a manufacturer to overcome the prima facie violation [30]. The bill includes a safety exception for a "hard" switch that was taken "for reasons related to the safety risk to patients" of the product [31]. The bill also includes a supply disruption exception for a "hard" switch (not associated with a delisting) in response to a supply disruption outside of the manufacturer's control that "cannot be remedied by reasonable efforts" [32]. To justify a "soft" switch, the bill requires a showing that the manufacturer had "legitimate pro-competitive reasons, apart from the financial effects of reduced competition," for its actions [33]. For all three justifications, the manufacturer must show that the switch would have been undertaken "regardless of whether" the generic or biosimilar had already entered the market [34]. The FTC may rebut the evidence presented by the manufacturer in support of its justification or overcome the justification by showing that the pro-competitive benefits of the conduct do not outweigh the anticompetitive effects [35].
- **Remedies:** The bill allows the FTC, in addition to any other available remedies, to recover in federal court disgorgement of any unjust enrichment obtained because of the violation as well as restitution [36]. While the Supreme Court recently ruled that the FTC does not have the authority under Section 13(b) of the FTC Act to seek equitable monetary relief such as restitution or disgorgement [37], this bill, if passed, would give the FTC a new authority to seek monetary relief outside administrative proceedings for prohibited product switches.

Stop STALLING Act ("H.R. 2374")

The Stop STALLING Act would create a presumption that a citizen petition is a sham and an unfair competition violation of the FTC Act if the FDA—not the FTC—determines that the petition was submitted with the "primary purpose" of delaying generic or biosimilar competition and was part of a series of petitions. Federal law permits a drug manufacturer to file a citizen petition with the FDA raising scientific and legal issues relating to a generic or biosimilar product regulated by the FDA and requesting that the FDA take, or refrain from taking, any administrative action [38]. As a general matter, efforts to petition the government, including the FDA, by way of citizen petitions, are immune from antitrust scrutiny under the Noerr-Pennington doctrine [39], unless the petitioning activity is shown to be objectively baseless and made with the intent of stifling competition, i.e., a "sham" [40]. Currently, the FDA is required to act on certain citizen petitions involving generic or biosimilar products within 150 days to avoid approval delay [41], and may identify petitions judged by the FDA to have been submitted with the primary purpose of delaying approval in its denial of the petition and its annual reports to Congress, as well as refer such petitions

to the FTC [42]. This bill, however, would create a presumption in an FTC enforcement action that the petitioning was a "sham" based on the FDA's determination regarding the "primary purpose" of a petition and shift to the manufacturer the burden of rebutting that presumption. Key takeaways include:

- **Violation and Lowered Standard for Unlawful Activity:** The bill provides that "sham" petitioning to the FDA concerning generic or biosimilar product approvals is an unfair method of competition under Section 5 of the FTC Act and empowers the FTC to seek civil penalties and other relief for a violation. A "sham" as defined by the bill means a petition that is both "objectively baseless" and an "attempt to use a governmental process (as opposed to the outcome of that process) to interfere with the business of a competitor" [43]. Notably, for a series of petitions, the first requirement regarding "objectively baseless" does not apply, leaving only the second criterion focused on subjective intent. Courts currently are divided on whether the "objectively baseless" requirement for the "sham" exception to Noerr-Pennington protection from antitrust liability can be dispensed with when dealing with a series or pattern of activity [44].
- **Presumption of Violation Based on FDA Determination:** If the FDA determines that one petition in a series of petitions "was submitted with the primary purpose of delaying the approval" of a generic or biosimilar drug, and provides a "reasonable basis" for that determination to the FTC, then the bill creates a presumption that the series of citizen petitions is a "sham" and thus a violation [45]. As a practical matter, this provision gives the FDA the power to determine that there has been a presumptive violation of Section 5 of the FTC Act.
- **Burden on Defendant to Rebut Presumption:** To rebut the presumption triggered by the FDA's "primary purpose of delay" finding, the defendant must establish that the series of petitions "is not a sham" [46]. The bill does not address how this would work in practice [47].
- **Civil Penalties:** In addition to any other available remedies, the FTC shall recover a civil penalty for each violation up to the revenue earned from the sale of any drug product related to the sham petition during the period when the petition was under review or \$50,000 for each calendar day that the sham petition was under review whichever is greater [48].

Affordable Prescriptions for Patients through Improvements to Patent Litigation Act ("H.R. 3991")

The Affordable Prescriptions for Patients through Improvements to Patent Litigation Act applies to patent infringement claims coming out of the "patent dance" information exchange created by the Biosimilar Products Competition Innovation Act ("BPCIA") [49]. For certain patents—ones that either have an actual filing date of more than four years after the brand reference product was approved or include a claim to a method in a manufacturing process that is not used by the brand—the bill limits brand biologic drug makers to asserting no more than 20 patents in an infringement action filed prior to commercial marketing of the biosimilar [50]. The bill further requires that no more than 10 of those 20 patents issued after the brand manufacturer gave its initial list of patents to the biosimilar applicant during the "patent dance" information exchange [51]. Key takeaways include:

- **Exceptions and Limitation:** A court may increase the 20-patent limit if justice requires or upon a showing of good cause, which requires the brand manufacturer to show that the biosimilar's abbreviated Biologics License Application fails to provide required information that would enable the brand manufacturer to determine the reasonableness of asserting an infringement claim [52]. The bill's limit does not apply to patents that claim a method for using a biological product in therapy, diagnosis, or prophylaxis [53].

Implications of the Four Proposed Bills

If passed, any one of these bills could have a significant impact on antitrust compliance or patent enforcement in the pharmaceutical industry. Collectively, the bills would create substantial changes and uncertainty. Implications include:

- **Patent settlements in which the alleged infringer receives anything of "value" beyond early entry and litigations costs would be presumptively unlawful:** Patent settlements with provisions beyond an earlier entry date (and a limited payment for legal fees) would become in most instances presumptively anticompetitive. Further, any licensing or business deal made at or around the time of the settlement might be said to provide "value" to the alleged infringer. Regardless of how reasonable and pro-competitive, any such deal would then trigger the presumption of a violation, placing the burden on the settling parties to disprove that presumption under a heightened burden of clear and convincing evidence. These changes would be a substantial shift in current antitrust rule-of-reason analysis, which places the burden on plaintiff to prove anticompetitive effects, and does not saddle defendants with a heightened clear and convincing standard for showing pro-competitive justifications. Moreover, such a presumption would kick in regardless of whether the product at issue was just one of many choices for patients and doctors in a crowded therapeutic category.
- **"Soft" switches to a new version of an existing drug could be illegal, discouraging important innovation:** Manufacturers may shy away from seeking to introduce new versions of an existing product for fear of having to continue to sell both the old and new versions in perpetuity to avoid a presumption of unlawful "product hopping." Despite case law supporting the legality of "soft" switching, a presumption of anticompetitive harm may lead manufacturers to deem even that strategy too risky, especially when there is no clear guidance on what conduct could be said to "unfairly disadvantage" a generic or biosimilar. Manufacturers may be unwilling to take on the presumption of anticompetitive harm and burden of litigating whether a shift in marketing and sales dollars to the new product from the old one, which is typical in a "soft" switch, was done for "legitimate pro-competitive reasons, apart from the financial effects of reduced competition."
- **Chilling effect on constitutionally protected petitioning activity:** Allowing the FDA to determine whether a citizen petition was submitted with the "primary purpose" of delaying generic or biosimilar competition, and thereby potentially creating a presumption it was unlawful, may discourage the exercise of protected petitioning rights.
- **Increased strategic challenges for patent holders seeking to enjoin infringement prior to biosimilar launch:** Creating a cap on the number of patents that can be asserted in patent litigation following the "patent dance" does not just artificially limit brand manufacturers' ability to enjoin infringement prior to the launch of the biosimilar. The cap also may force brand manufacturers to make a hurried decision on which patents they perceive to be the "strongest" without the opportunity to conduct full discovery on the biosimilar product. The brand manufacturer, however, would still retain the right to assert patents not subject to the 20-patent limit, such as patents filed during the development of its biologic product and patents claiming manufacturing methods actually used by the brand manufacturer [54].
- **Potential uptick in private enforcement:** The three proposed amendments to the FTC Act may affect private actions as well. While the bills do not provide for private enforcement under the FTC Act, plaintiffs likely would try to take advantage of the presumptions created by these bill, primarily through creative use of state analogues to Section 5 of the FTC Act that provide for private actions [55].

We should expect increased uncertainty as the parameters of the bills, if turned into law, are fleshed out in practice and through litigation.

[1] Preserve Access to Affordable Generics and Biosimilars Act, S. 64, 116th Cong. (2019), <https://www.congress.gov/bill/116th...>

[2] Affordable Prescriptions for Patients through Promoting Competition Act, H.R. 4398, 116th Cong. (2019), <https://www.congress.gov/bill/116th...>

[3] Stop STALLING Act, H.R. 2374, 116th Cong. (2020), <https://www.congress.gov/bill/116th...>

[4] Affordable Prescriptions for Patients through Improvements to Patent Litigation Act, H.R. 3991, 116th Cong. (2019), <https://www.congress.gov/bill/116th...>

[5] Press Release, Chairman Frank Pallone, Jr., House Comm. on Energy & Com., Pallone Remarks at Legislative Hearing to Lower the Cost of Prescription Drugs (May 4, 2021), <https://energycommerce.house.gov/ne...>; Lower Drug Costs Now: Expanding Access to Affordable Health Care, Health, Emp., Lab., and Pensions Subcomm. of the Comm. on Educ. and Lab. (May 5, 2021), <https://edlabor.house.gov/hearings/...>; Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2020), <https://www.congress.gov/bill/116th...>

[6] *FTC v. Actavis, Inc.*, 570 U.S. 136, 156 (2013).

[7] See *id.*

[8] S. 64§ 3(a).

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.* at § 5.

[18] Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066, 2461-64 (2003) (codified as amended at 21 U.S.C. § 355(j)).

[19] Pub. L. No. 108-173, §1112.

[20] S. 64 § 4.

[21] Assemb. B. 824 § 134002(a)(1), 2019 Leg. (Cal. 2019). See also Kristen O’Shaughnessy et. al., California’s New Reverse Payment Law Departs from Supreme Court Standard in *FTC v. Actavis*, <https://www.whitecase.com/publications/alert/californias-new-reverse-payment-law-departs-supreme-court-standard-ftc-v-actavis> ↗.

[22] Assemb. B. 824 § 134002(a)(1).

[23] Id. at § 134002(a)(2).

[24] Id. at § 134002(e)(1)(A).

[25] Id. at § 134002(c); see also O’Shaughnessy, supra note 23.

[26] Id.

[27] Id.

[28] Id.

[29] Id.

[30] Id.

[31] Id.

[32] Id.

[33] Id.

[34] Id.

[35] Id.

[36] Id.

[37] *AMG Capital Mgmt., LLC v. FTC*, 141 S. Ct. 1341 (2021).

[38] 21 C.F.R. § 10.30 (2021).

[39] The Noerr-Pennington doctrine is grounded in First Amendment principles and protects from antitrust scrutiny certain activity that involves petitioning the government for redress. See E.

R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 139–40 (1961); United Mine Workers v. Pennington, 381 U.S. 657, 678 (1965).

[40] Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60 (1993).

[41] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144 §§ 106, 1135, 126 Stat. 993 (2012) (amending Section 505(q) of the Food, Drug, and Cosmetic Act by reducing the deadline for responding to citizen petitions from 180 days to 150 days). See also Ctr. For Drug Evaluation & Rsch., FDA, U.S. Dep't of Health & Hum. Servs., Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Fed. Food, Drug, and Cosmetic Act 3 (2011) [hereinafter "FDA, Guidance on Citizen Petitions"].

[42] FDA, Guidance on Citizen Petitions, *supra* note 49, at 16–17.

[43] H.R. 2374 § (2)(a)(6).

[44] See Dylan Carson and Scott Russell, "Circuits Reinforce Split over When Noerr-Pennington Shields Serial Litigants," Antitrust Source (Feb. 2021), https://www.americanbar.org/content/dam/aba/publishing/antitrust_source/2021/feb-2021/at-source-feb2021-carson.pdf ↗

[45] *Id.* at § (2)(c)(2).

[46] *Id.* at § 2(c)(2).

[47] *Id.* at § 2(a)(6) (defining "sham").

[48] *Id.* at § 2(c)(4).

[49] The "patent dance" information exchange is described in 42 U.S.C. § 262(l). When the biosimilar applicant chooses the "patent dance" process, the submission of the biosimilar application to FDA is treated as an artificial act of infringement. See 35 U.S.C. § 271(e)(2)(c).

[50] H.R. 3991 § 2(a)(2) (2019).

[51] *Id.*

[52] *Id.* at § 2(c).

[53] *Id.* at § 2(e).

[54] *Id.*

[55] See Justin J. Hakala, Follow-On State Actions Based on the FTC's Enforcement of Section 5 at 6, App. A (2008).