IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re: LAMICTAL DIRECT PURCHASER ANTITRUST LITIGATION **THIS DOCUMENT RELATES TO: ALL ACTIONS**	**Master File No.: 12-995 (WHW-MCA)**

FEDERAL TRADE COMMISSION BRIEF AS *AMICUS CURIAE*

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The Third Circuit recently held that a court considering an antitrust challenge to a Hatch-Waxman patent settlement "must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012), *petition for cert. filed*, 81 U.S.L.W. 3090 (U.S. Aug. 24, 2012) (No. 12-245). Quoting a Federal Trade Commission decision, the court agreed that "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry." *Id.* at 218 (quoting *In the Matter of Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003)). "[R]everse payments," the court observed, "permit the sharing of monopoly rents between would-be competitors" and so provide protection from competition "not on the strength of a patent holder's legal rights, but on the strength of its wallet." *Id.* at 216–17. The *K-Dur* court applied its rebuttable presumption to "any payment" and did not distinguish between different forms of payment. *Id.*

A question now before this Court is whether the Plaintiffs have plausibly alleged a reverse payment triggering a rebuttable presumption under *K-Dur*. The complaint alleges that GlaxoSmithKline ("GSK") paid Teva to delay entry through promises not to compete with authorized generic ("AG") versions of the drug Lamictal (GSK's "no-AG commitments"). Defendants, however, insist that the no-AG commitments cannot be payments under *K-Dur*. They claim instead that (1) Teva received nothing more than the ability to market its generic product based on a "negotiated entry date," a type of settlement permitted under *K-Dur*; and (2) exclusive licenses are not subject to antitrust scrutiny.

Both of Defendants' claims are incorrect. First, Teva received more than the right to enter on a negotiated entry date—it is undisputed that it also received commitments that GSK would

not market AG versions of the two Lamictal products. As such, they guaranteed that Teva would be protected from generic competition on each of its generic Lamictal products for at least six months. In the unique context of the Hatch-Waxman Act, such commitments are often quite lucrative to the generic. Thus, as with the cash payment in *K-Dur*, it is logical to conclude that each of these commitments could have acted as the *quid pro quo* for Teva to accept a later entry date than it otherwise would have.

Second, while in many contexts exclusive patent licenses may be procompetitive, they are not necessarily so, nor are they immune from antitrust scrutiny. Indeed, a case relied upon by Defendants explicitly notes that "[t]hough the grant of an exclusive license is not per se a violation of the antitrust laws, it may be an instrument by which an unlawful restraint of trade or a monopoly is created." *Benger Labs. Ltd. v. R. K. Laros Co.*, 209 F. Supp. 639, 648 (E.D. Pa. 1962). In direct contravention of the Third Circuit's holding in *K-Dur*, both of Defendants' arguments rely on superficial labels rather than the actual substance of the agreements at issue. Although GSK and Teva effected the no-AG commitments through exclusive licenses, the legal form of the agreements does not alter the "economic realities," which is the required focus of the Third Circuit's rule. *See K-Dur*, 686 F.3d at 218 (requiring an antitrust analysis "based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties.").

The FTC submits this brief as *amicus curiae* to assist the Court in its analysis of the economic realities of a no-AG commitment.[1] It presents data from a comprehensive empirical study, conducted by the FTC at the request of Congress, on the effects of AGs on branded drug firms, on generic drug firms, and on consumers. This empirical evidence confirms what the

[1] The FTC's brief does not address the other arguments raised by the Defendants and should not be construed as agreeing or disagreeing with those arguments.

pharmaceutical industry has long understood: that a no-AG commitment is undoubtedly a payment, providing a convenient method for branded drug firms to pay generic patent challengers for agreeing to delay entry.

I. Interest of the Federal Trade Commission

The Federal Trade Commission is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws.[2] It exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry. Over the past decade, the Commission has used its law enforcement authority to challenge Hatch-Waxman patent settlements involving payments to delay entry by a lower-priced generic drug (sometimes referred to as "reverse payments," "exclusion payments," or "pay-for-delay").[3]

In addition to its role as a law enforcement agency, the FTC has a congressionally-mandated role to conduct studies of industry-wide competition issues. To fulfill this role, Congress granted the agency broad authority to compel the production of data and information not directly related to any law enforcement investigation.[4] This authority gives the agency a unique capacity to conduct "systematic, institutional study of real-world industries and activities"

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[2] 15 U.S.C. §§ 41–58.

[3] *See, e.g.*, First Am. Compl., *FTC v. Cephalon, Inc.*, No. 08-2141, Doc. No. 40 (E.D. Pa. filed Aug. 12, 2009); *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *petition for cert. filed* (U.S. Oct. 4, 2012) (No. 12-416); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[4] The FTC has authority "[t]o require, by general or special orders, persons, partnerships, and corporations, engaged in or whose business affects commerce . . . to file with the Commission in such form as the Commission may prescribe . . . reports or answers in writing to specific questions, furnishing to the Commission such information as it may require as to the organization, business, conduct, practices, management, and relation to other corporations, partnerships, and individuals." 15 U.S.C. § 46(b).

that "modern academic research in industrial organization rarely undertakes."[5] Courts, including the Supreme Court, have relied on FTC studies when resolving legal and policy issues.[6] The Third Circuit repeatedly cited FTC reports in its *K-Dur* decision.[7]

The Commission has conducted a variety of empirical studies covering the pharmaceutical industry. Of particular relevance to the pending motion to dismiss is the FTC's comprehensive empirical study of AGs that resulted in a detailed 270-page report published in 2011.[8] This study includes analysis of the competitive implications of patent litigation settlements in which brand companies agree to refrain from offering an AG when the generic company agrees to defer its entry.

II. Background on Authorized Generics, No-AG Commitments, and Exclusive Licenses

Through enactment of the Hatch-Waxman Act, Congress established the regulatory framework under which a generic drug manufacturer may obtain approval of its product from the Food and Drug Administration. To encourage generic entry as soon as warranted, the Act establishes certain rights and procedures that apply when a company seeks FDA approval to market a generic product before expiration of the patent(s) covering the counterpart brand-name drug. In such cases, the generic applicant must certify that the patent in question is invalid or not infringed by the generic product, known as a "Paragraph IV" certification. The Hatch-Waxman

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[5] *Report of the American Bar Association Section of Antitrust Law, Special Committee to Study the Role of the Federal Trade Commission*, 58 ANTITRUST L.J. 43, 103 (1989).

[6] *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, — U.S. —, 132 S. Ct. 1670, 1678 (2012) (citing an FTC study on generic pharmaceuticals); *Granholm v. Heald*, 544 U.S. 460, 466–68, 490–92 (2005) (citing repeatedly to an FTC study of Internet wine sales); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 754 n.11, 765 n.20 (1976) (referring to an FTC study concerning drug price advertising restrictions).

[7] *See K-Dur*, 686 F.3d at 208, 215, 218 (citing three FTC reports).

[8] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf [hereinafter AG Report].

Act awards the first generic company to file an application with a Paragraph IV certification (the "first filer") 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's generic drug application.[9]

The 180-day marketing exclusivity does not, however, preclude a brand company from marketing an AG.[10] An AG is chemically identical to the branded drug, but sold as a generic product under the same FDA approval as the branded drug. Brand companies frequently launch AGs to compete with first-filer generics during Hatch-Waxman exclusivity and capture sales that would otherwise go to the first filer. As discussed below, competition from an AG during this otherwise-exclusive marketing period has a substantial impact on the first-filer generic's revenue. To prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand company's agreement not to launch an AG.

A no-AG commitment can take a variety of forms. For example, the brand company might explicitly agree not to compete using an AG during the generic's exclusivity period, or it might designate the first-filer generic as the exclusive distributor of the brand's AG. The most common form of a no-AG commitment, however, has been the brand company granting the first-filer generic company an exclusive license to market a generic product.[11] Because the license is exclusive as to *all* generic versions of the drug, it prevents the brand company from marketing an AG in competition with the licensed generic company.

[9] 21 U.S.C. § 355(j)(5)(B)(iv).

[10] *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005).

[11] *See* AG Report, *supra* note 8, at 144.

III. A No-AG Commitment Functions as a Payment that Can Induce a Generic Company to Accept a Delayed Entry Date

In its *K-Dur* decision, the Third Circuit held that judicial analyses of reverse payment antitrust cases should be "based on the economic realities of the reverse payment settlement," not "the labels applied by the settling parties."[12] In its 2011 AG Report, the FTC recognized that a no-AG commitment provides significant value to a first-filer generic company and has become "a common form of compensation to generics" to induce delayed entry; it "should therefore be analyzed in the same manner as other forms of consideration paid to generics."[13]

A. Competition from an Authorized Generic Significantly Reduces the Revenues that a Generic Company Otherwise Would Obtain from Its 180-Day Marketing Exclusivity

In the AG Report, the FTC analyzed documents and empirical data covering more than a hundred companies and found that "the presence of authorized generic competition reduces the first-filer generic's revenues by 40 to 52 percent, on average," during the 180-day exclusivity period.[14] The FTC found that a generic company makes significantly less when competing against an AG because: (1) the AG takes a significant share of generic sales away from the first filer;[15] and (2) wholesale and retail prices decrease when the first filer faces an AG.[16] For the

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[12] *K-Dur*, 686 F.3d at 218.

[13] AG Report, *supra* note 8, at i.

[14] *Id.* at iii; *see also id.* at 33. In fact, the report notes that the effects of an AG actually continue well after first-filer exclusivity expires, as "[r]evenues of the first-filer generic manufacturer in the 30 months *following* exclusivity are between 53 percent and 62 percent lower when facing an AG." *Id.* at iii (emphasis added).

[15] *Id.* at 57–59 (concluding that a first filer loses more than 25% of the market when it competes against an AG during first-filer exclusivity); *see also* FTC, *Authorized Generics: An Interim Report*, at 3 (2009), *available at* http://www.ftc.gov/os/2009/06/P062105authorized genericsreport.pdf (observing that "the AG represents a very close substitute for the ANDA generic and therefore typically obtains significant market share at the expense of the ANDA generic").

[16] AG Report, *supra* note 8, at 41–48.

first-filer generic of a $2.2 billion branded product like Lamictal, the difference between selling the only generic product and competing against an AG during the exclusivity period is considerable, likely amounting to hundreds of millions of dollars.[17]

These economic realities are well known in the pharmaceutical industry, and the FTC's AG Report cites numerous documents from industry participants confirming the financial impact of an AG.[18] For example, one generic company stated that "[d]ue to market share and pricing erosion at the hands of the authorized player, we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario."[19]

Another generic company, Apotex, quantified the financial repercussions of facing an AG for the brand drug Paxil. In a letter to the FDA, Apotex described how the AG reduced its revenues by approximately $400 million:

> Prior to launch, Apotex expected sales for its paroxetine product [generic Paxil] to be in the range of $530–575 million during the 6-month exclusivity period. Given competition from [the brand company's] authorized generic product, Apotex only generated $150–200 million in total sales. There can be no doubt that the [brand company's] authorized generic crippled Apotex' 180-day exclusivity—it reduced Apotex' entitlement by two-thirds—to the tune of approximately $400 million.[20]

These examples demonstrate the significant financial ramifications that a brand company's AG can have on the first-filer generic company and the incentives a no-AG commitment can provide to a generic company to delay generic entry.

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[17] *See, e.g., id.* at 80; *see also infra* notes 20, 23 and accompanying text.

[18] These materials were collected from generic and brand companies under the FTC's broad authority to compel production of data outside of a law enforcement investigation. *See* 15 U.S.C. § 46(b).

[19] AG Report, *supra* note 8, at 81.

[20] Comment of Apotex Corp. in Supp. of Citizen Pet. of Mylan Pharms., Inc., at 4, No. 2004P-0075/CP1 (F.D.A. Mar. 24, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf.

B. A No-AG Commitment Enables the Generic Company to Maximize Its Revenues During the First-Filer Exclusivity Period

The only way for a first filer to ensure that it will not face AG competition during its exclusivity period is to obtain a commitment from the brand company that it will not launch a competing AG. By executing a no-AG commitment, in effect, "the brand agrees not to subtract from the generic's profits during the 180-day period."[21] This commitment, therefore, is highly valuable to the first-filer generic. With a no-AG commitment, "the first-filer's revenue will approximately double" during the 180-day exclusivity period, compared to what the first filer would make if it competed against an AG.[22] To put this impact in real dollars, Apotex's experience facing an AG version of Paxil, described *supra*, is instructive. The U.S. sales of Paxil were roughly equivalent to those of Lamictal in the year before each product faced generic competition ($2.3 billion and $2.2 billion, respectively).[23] Apotex estimates that it would have earned approximately $400 million more absent the AG.[24] Thus, in this case, GSK's agreement not to launch an AG version of Lamictal tablets during Teva's first-filer exclusivity period may have increased Teva's revenues by hundreds of millions of dollars.

Teva itself acknowledged the economic realities of a no-AG commitment in its 2008 annual report filed with the Securities and Exchange Commission. According to Teva, its generic

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[21] FTC Staff, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 5 (2010), *available at* http://www.ftc.gov/os/2010/01/100112 payfordelayrpt.pdf.

[22] AG Report, *supra* note 8, at vi.

[23] *See Top 200 Brand Drugs by Retail Dollars in 2002*, DRUG TOPICS (Apr. 7, 2003), http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id=115428 (reporting $2.3 billion in Paxil sales in 2002); Press Release, Teva Pharm. Indus. Ltd., Teva Introduces First Generic Lamictal® Tablets in the United States (July 23, 2008) (reporting annual Lamictal sales of $2.2 billion for the twelve-month period ending March 31, 2008), *available at* http://www.tevapharm.com/Media/News/Pages/2008/1554751.aspx.

[24] Comment of Apotex Corp. in Supp. of Citizen Pet. of Mylan Pharms., Inc., at 4, No. 2004P-0075/CP1 (F.D.A. Mar. 24, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf.

Lamictal product generated "substantially increased" revenues because it did not face generic competition during the first-filer exclusivity period. As Teva explained:

> To the extent that we succeed in being the first to market a generic version of a significant product, and particularly if we obtain the 180-day period of market exclusivity for the U.S. market provided under the Hatch-Waxman Act, our sales, profits and profitability can be substantially increased . . . prior to a competitor's introduction of an equivalent product. For example, our 2008 operating results included major contributions from products sold with U.S. market exclusivity, such as lamotrigine [generic Lamictal].[25]

To guarantee that it will achieve these "substantially increased" revenues, generics have strong incentives to get a no-AG commitment from the brand company.

As discussed above, the most common form of no-AG commitment is an exclusive license, which accomplishes the effect of excluding the brand company's AG under the guise of an unremarkable business arrangement. In other circumstances, exclusive licenses can promote competition by facilitating efficient investment in a product. But in the context of Hatch-Waxman settlements between a brand company and a first-filer generic company, the purpose and practical effect of an exclusive license (or any other form of no-AG commitment) is to prevent competition between a brand's AG product and the first-filer generic's product during the marketing exclusivity period.

For that reason, an exclusive license with a first filer is different from a non-exclusive license. The latter simply conveys to the generic company the right to enter and compete with its generic product. It is this type of "negotiated entry date" that the Third Circuit insulated from its

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[25] Teva Pharm. Indus. Ltd., Annual Report (Form 20-F), at 5 (Feb. 27, 2009); *see also Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1903 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 110th Cong. 14 (2007) (statement of Theodore C. Whitehouse of Wilkie, Farr & Gallagher LLP on behalf of Teva Pharms. USA, Inc.), *available at* http://www.ipo.org/AM/Template.cfm?Section=Past_Meetings_and_Events&Template=/CM/ContentDisplay.cfm&ContentID=18298 (discussing the value of an exclusive license to a first filer).

K-Dur presumption of illegality.[26] Under such a license, the revenues generated by the generic company derive entirely from the generic's own ability to market its product. Thus, a non-exclusive license, standing alone, does not compensate the generic company for deferring its entry. This is very different from the grant of an exclusive license, where up to half of the generic company's revenues result from the brand company's commitment not to compete with an AG.[27]

C. In Light of These Economic Realities, a No-AG Commitment Is a Payment to the Generic Company for Delayed Entry

Because non-exclusive licenses and exclusive licenses in patent settlements with first filers have distinctive ramifications for the generic drug company, the FTC has consistently regarded them differently. The former creates competition, whereas the latter can be a tool to induce a generic company to accept a later entry date than it otherwise would, absent the brand company's commitment to share the monopoly profits generated by delayed generic entry.

Despite the clear financial benefits of an exclusive license or other no-AG commitment to a first-filer generic company, Defendants suggest that the Third Circuit's recent *K-Dur* decision is limited to monetary payments.[28] Nowhere does the court make such artificial distinctions about the form of compensation, referring instead to "*any* payment from a patent holder to a generic patent challenger who agrees to delay entry."[29] Accepting Defendants' argument that the

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[26] *See K-Dur*, 686 F.3d at 217–18 ("[N]othing in the rule of reason test that we adopt here limits the ability of the parties to reach settlements based on a negotiated entry date for marketing of the generic drug.").

[27] *See supra* note 14 and accompanying text.

[28] Mem. in Support of the Teva Defs.' Mot. to Dismiss Direct Purchaser Pls.' Consol. Am. Class Action Compl. at 23–24, No. 12-995, Doc. No. 71 (filed Aug. 15, 2012).

[29] *K-Dur*, 686 F.3d at 218 (emphasis added). Black's Law Dictionary defines "payment" as "Performance of an obligation by the delivery of money *or some other valuable thing* accepted in partial or full discharge of the obligation." BLACK'S LAW DICTIONARY (9th ed. 2009) (emphasis added).

K-Dur holding applies only to monetary payments would effectively nullify the Third Circuit's decision and permit anticompetitive settlements to proceed unchecked.

Indeed, the economic realities of no-AG commitments require that such promises be analyzed like other forms of compensation paid to generics. Practically, a no-AG commitment has the same capacity to purchase delay as a monetary payment. When a brand competes through an AG, it siphons substantial revenues from the first-filer generic company. When the brand agrees to forgo selling an AG, it essentially hands these revenues back to the first-filer generic company and, in return, gets a delayed generic entry date. The FTC's AG Report describes how one brand company recognized that a no-AG commitment could maximize "the combined net present value of both companies' products":

> [T]he brand-name company's documents show that if it launched an AG to compete with the first-filer generic during its 180 days of marketing exclusivity, the net present value of the generic's product would decline by nearly a third. If, however, the brand agreed not to offer an AG, and the generic agreed to further delay its entry in exchange for that agreement, the combined net present value of both companies' products would be maximized. [30]

In this manner, no-AG commitments are mutually beneficial to settling brand and generic pharmaceutical companies. The brand company benefits from the additional delay in generic entry, while the generic company benefits by not facing competition from an AG during its 180-day exclusivity. Both effects are harmful to consumers, who face higher drug prices over a longer period.

Because the brand and generic companies benefit from no-AG commitments, they have become a common form of payment to generic companies. One recent FTC report on pharmaceutical patent settlements shows that more than half of the settlements classified as

[30] AG Report, *supra* note 8, at 142 (summarizing a brand company's ordinary course document submitted to the FTC as part of its study of AGs).

containing payments from brand companies to first-filer generics involved a no-AG commitment similar to the one in the Lamictal settlement.[31] After the FTC began challenging cash-only reverse payments, pharmaceutical companies turned to other payment methods in what one pharmaceutical industry observer described as a "sophisticated version of three-drug monte" designed to evade antitrust scrutiny.[32] Allowing pharmaceutical companies to sidestep the *K-Dur* rule by simply making non-cash payments would elevate form over substance, in direct contravention of the *K-Dur* court's instruction to credit "the economic realities of the reverse payment settlement rather than the labels applied by the settling parties."[33]

IV. Treating No-AG Commitments as Payments Will Not Impair Patent Settlements

Defendants assert that if no-AG commitments "were considered 'payments' under *K-Dur*, then *K-Dur* would permit no patent settlements at all."[34] But this is not true, and the empirical data on Hatch-Waxman settlements collected by the FTC over an eight-year period amply belie this doomsday scenario. While no-AG commitments represent a large portion of the agreements involving reverse payments in recent years—and likely billions of dollars of higher

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[31] *See* AG Report, *supra* note 8, at 145 ("The 15 agreements in FY 2010 in which brand-name firms agreed not to introduce an AG were nearly 60% of the 26 agreements that year containing payments to a first-filer and a restriction on that firm's ability to market its product.").

[32] Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 96 (2009) ("[B]rand firms no longer are making simple payments to generics to stay off the market. Such settlements, which appear quaint in contrast to today's sophisticated version of three-drug monte, are no longer observed in today's marketplace. Instead, a brand's promise not to introduce an authorized generic, accompanied by an ANDA generic's agreement to delay entering the market, could allow the brand to reap millions of dollars in additional profits while also benefitting the ANDA generic. At the same time, such a payment is more difficult to quantify and appears less suspicious to an antitrust court that is trained to look for monetary payments.").

[33] *K-Dur*, 686 F.3d at 218.

[34] Mem. in Support of the Teva Defs.' Mot. to Dismiss Direct Purchaser Pls.' Consol. Am. Class Action Compl. at 23, No. 12-995, Doc. No. 71 (filed Aug. 15, 2012).

drug costs for consumers[35]—these commitments are still a small minority of Hatch-Waxman settlements generally. Of the nearly 500 final pharmaceutical patent settlements filed with the FTC under the Medicare Modernization Act (MMA)[36] from 2004 through the end of the 2011 fiscal year, fewer than 60 (approximately 11 percent) have included a no-AG commitment.[37] Holding this limited number of agreements to a presumption of illegality will not prevent all patent settlement as Defendants predict.[38]

In the broader context, the data conclusively demonstrate that pharmaceutical companies can—and in most cases, do—settle patent litigation without reverse payment *of any kind*, including exclusive licenses or other no-AG commitments. As the Third Circuit observed in *K-Dur*, its rebuttable presumption "will leave the vast majority of pharmaceutical patent settlements unaffected."[39] The Court cited a 2011 FTC report to support its conclusion that "nearly seventy-five percent of Hatch-Waxman Act infringement suits that settled in 2010 did so

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[35] *See* AG Report, *supra* note 8, at 140.

[36] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (codified at 21 U.S.C. § 355) [hereinafter MMA] (requiring the filing of pharmaceutical patent settlement agreements with the FTC and the Department of Justice). The FTC's Bureau of Competition publishes annual reports summarizing these filings, *available at* http://www.ftc.gov/bc/healthcare/drug/index.htm.

[37] *See* AG Report, *supra* note 8, at 144; FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2011*, at 1 (2011), *available at* http://www.ftc.gov/os/2011/10/1110mmaagree.pdf.

[38] Even though finding a payment creates a presumption of anticompetitive conduct, it does not necessarily mean that the settlement is an unreasonable restraint of trade. The *K-Dur* decision explicitly identifies potential justifications for the payment. For example, a defendant may show that the payment was not for delay. *K-Dur*, 686 F.3d at 218. The Commission has long taken the position that a small payment less than saved litigation expenses may not be intended to delay generic entry. *See, e.g.*, Br. of Resp't Fed. Trade Comm'n at 45, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688); Bristol-Myers Squibb Co., Analysis To Aid Public Comment, 68 Fed. Reg. 12080, 12087 (Mar. 13, 2003).

[39] *K-Dur*, 686 F.3d at 218.

without reverse payments."[40] Since the FTC has consistently classified no-AG commitments as a form of compensation from the branded drug company to the generic,[41] the 75 percent figure cited by the Third Circuit already accounts for no-AG commitments as a subset of reverse payments. Furthermore, analyzing the FTC's broader data set provides the same result: of the hundreds of final patent settlements filed between 2004 and 2011, 74 percent involved no compensation—cash, no-AG commitment, or otherwise—from the brand to the generic in combination with a restriction on generic entry.[42] Therefore, it is impossible to harmonize Defendants' theory—that finding a no-AG commitment to be a payment will prevent all settlement—with the data.

Thus, contrary to Defendants' characterization, the question before this Court relates to only a narrow class of patent settlements: those in which the brand company guarantees a generic company a period of exclusive marketing. Because these no-AG commitments appear in only a small fraction of pharmaceutical settlements, a finding that a no-AG commitment is a payment will not impair the ability of pharmaceutical companies to reach settlement, nor will it prohibit exclusive licenses in procompetitive contexts outside of the Hatch-Waxman pharmaceutical framework.

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[40] *Id.*

[41] *See, e.g.*, FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007*, at 3 (2008) ("In eleven of the final settlements containing compensation to the generic and a restriction on the generic company's ability to market its product, the compensation took the form of an agreement by the brand company not to launch or sponsor an authorized generic for a period of time after the entry of the generic company's product.").

[42] *See* FTC Bureau of Competition's annual reports detailing the agreements filed in each fiscal year from 2004 to 2011, titled *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, *available at* http://www.ftc.gov/bc/healthcare/drug/index.htm.

V. Conclusion

The FTC respectfully requests that the Court carefully consider the economic realities of no-AG commitments and their impact on consumers as it addresses the questions before it. The FTC would be pleased to address any questions the Court may have, including by participation at any hearing, should the Court find it useful.

Dated: October 5, 2012

Respectfully submitted,

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