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

In re: EFFEXOR XR ANTITRUST LITIGATION **This Document Relates To:** **All Actions**	**Lead case no.: 3:11-cv-05479**

FEDERAL TRADE COMMISSION'S MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

The Federal Trade Commission respectfully moves for leave to file an *amicus curiae* brief in the above-captioned matter in connection with the Court's July 24, 2012 order to address the significance of the Third Circuit's *K-Dur* decision on the motions to dismiss pending in this case. *In re K-Dur Antitrust Litig.*, No. 10-2077, 2012 WL 2877662 (3d Cir. July 16, 2012).

A central issue arising from the parties' filings is whether a branded company's commitment not to launch an authorized generic ("AG") in competition with a generic company (a "no-AG" commitment) is a payment under the Third Circuit's ruling in *K-Dur*. *Id.* at *16 (holding 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.")

The FTC seeks leave to submit a brief as *amicus curiae* to assist the Court in its analysis of no-AG commitments and to correct mischaracterizations of the FTC's position on no-AG commitments contained in the Defendant's filings.[1] The FTC is an independent agency charged

[1] *See, e.g.*, Reply Mem. in Support of Teva Defs.' Motion to Dismiss All Direct Purchaser Compls., No. 11-05479, Doc. No. 166 (filed Aug. 3, 2012), at 11 (describing incorrectly a decade-old FTC advisory opinion to suggest that the Commission's treatment of no-AG commitments is "in line" with defendants' arguments); Letter Br. from Liza

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. 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.

As described in the *amicus* brief, the FTC has a unique institutional perspective—based on years of study and empirical analysis—to offer the Court in its analysis of the competitive implications of no-AG commitments. The *amicus* brief presents data from a comprehensive, 270-page 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 pharmaceutical industry has long understood: that a no-AG commitment provides a convenient method for brand drug firms to pay generic patent challengers for agreeing to delay entry.

Plaintiffs have consented to the Commission's filing of an *amicus* brief. Counsel for the Commission conferred with Defendants' counsel on August 7, 2012, and have not yet received a response.

Authority

"District courts have broad discretion to appoint amicus curiae." *Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 82 (D.N.J. 1993) (citations omitted). Although there is "no rule governing the appearance of *amicus curiae* in the United States District Courts," *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002), some federal

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M. Walsh to Judge Joel A. Pisano, No. 11-05479, Doc. No. 168 (filed Aug. 3, 2012), at 5 n.10 (drawing improper inferences from the Commission's use of its enforcement resources).

[2] 15 U.S.C. §§ 41–58.

district courts have looked to Federal Rule of Appellate Procedure 29 for guidance in exercising their broad discretion. *See, e.g.*, *id.* (explaining that Rule 29 requires *amici* to demonstrate that a proposed brief is timely, useful, and expresses a special interest not represented competently or at all in the case) (citation omitted). *Amici* should not be "partial to a particular outcome in the case" but need not be "totally disinterested." *Id.* (citations omitted). "Courts have found the participation of an amicus especially proper where the amicus will ensure complete and plenary presentation of difficult issues so that the court may reach a proper decision." *N.J. Prot. and Advocacy, Inc. v. Twp. of Riverside*, No. 04-5914, 2006 WL 2226332, at *5 (D.N.J. Aug. 2, 2006) (quoting *Liberty Res., Inc. v. Phila. Hous. Auth.*, 395 F. Supp. 2d 206, 209–10 (E.D. Pa. 2005)) (internal quotation marks omitted).

Argument

The FTC's brief as *amicus curiae* is timely, provides useful information to the Court, and expresses a special government interest not currently represented before the Court. It also corrects Defendants' misrepresentations of the FTC's position on no-AG commitments.

Conclusion

For the foregoing reasons, the Commission respectfully requests that the Court grant leave to file an *amicus curiae* brief.

Dated: August 10, 2012

Respectfully submitted,

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FEDERAL TRADE COMMISSION BRIEF AS *AMICUS CURIAE*

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Top 200 Brand Drugs by Retail Dollars in 2002, DRUG TOPICS (Apr. 7, 2003), http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id=115428 8

The Third Circuit has 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.*, — F.3d —, No. 10-2077, 2012 WL 2877662, at *16 (3d Cir. July 16, 2012). "[R]everse payments," the court observed, "permit the sharing of monopoly rents between would-be competitors" and so create incentives for collusion. *Id.* at *14. The court noted that allowing such conduct would enable a drug company to protect its intellectual property, "not on the strength of a patent holder's legal rights, but on the strength of its wallet." *Id.* at *15. Instead, the court established the presumption that such payments are unlawful, agreeing 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 *16 (quoting *In the Matter of Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003)). The *K-Dur* court applied its rebuttable presumption to "any payment" and did not distinguish between different forms of payment. *Id.* at *16.

A question currently before the Court is whether the plaintiffs have plausibly alleged a reverse payment triggering a rebuttable presumption under *K-Dur*. Plaintiffs contend Wyeth paid Teva to delay entry through its promise not to compete with an "authorized generic" ("AG") version of Effexor XR during Teva's 180-day exclusivity period (Wyeth's "no-AG commitment"). Wyeth and Teva do not dispute this no-AG commitment was extremely lucrative for Teva. Indeed, Teva has previously acknowledged that its revenues are "substantially increased" when it does not face competition from an AG during its exclusivity period. *See* Section III.B, *infra*.

Nonetheless, despite its economic value to Teva, Defendants insist that Wyeth's no-AG commitment is merely a garden-variety exclusive patent license and does not constitute a payment under *K-Dur*. They also contend the Federal Trade Commission in the past endorsed similar agreements. Defendants' arguments mischaracterize the position of the FTC with regard to such no-AG commitments. More fundamentally, they invite this Court to do precisely what the Third Circuit has forbidden—that is, rely on labels rather than economic realities. *See K-Dur*, 2012 WL 2877662, at *16 (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 the no-AG commitment. 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 pharmaceutical industry has long understood: that a no-AG commitment provides 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.[1] 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-

[1] 15 U.S.C. §§ 41–58.

priced drug (sometimes referred to as "reverse payments," "exclusion payments," or "pay-for-delay").[2]

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 accomplish this role, Congress granted the agency broad authority to compel the production of data and information not directly related to any law enforcement investigation.[3] This authority gives the agency a unique capacity to conduct "systematic, institutional study of real-world industries and activities" that "modern academic research in industrial organization rarely undertakes."[4] In the pharmaceutical area, the Commission has used this authority to conduct a comprehensive empirical study of AGs (resulting in a 270-page report), including 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.[5] Courts have relied on FTC studies when

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[2] *See* First Am. Compl., *FTC v. Cephalon, Inc.*, No. 08-2141 (E.D. Pa. filed Aug. 12, 2009); *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[3] 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).

[4] *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).

[5] *See* Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (Aug. 2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf [hereinafter AG Report]. *See also* reports prepared annually by FTC staff summarizing all pharmaceutical patent settlements filed with the FTC under the Medicare Modernization Act during the FTC's most recent fiscal year, *available at* http://www.ftc.gov/bc/healthcare/drug/index.htm (discussing the use of no-AG agreements in pharmaceutical patent settlements).

resolving legal and policy issues, including the Supreme Court[6] and the Third Circuit, the latter of which repeatedly cited FTC reports in *In re K-Dur Antitrust Litig.*, — F.3d —, No. 10-2077, 2012 WL 2877662, at *6, *13, *15 (3d Cir. July 16, 2012) (citing three FTC reports).

II. Background on Authorized Generics and No-AG Commitments

Through enactment of the Hatch-Waxman Act, Congress established the regulatory framework under which a generic manufacturer may obtain approval of its drug by 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 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 application.[7]

The 180-day marketing exclusivity does not, however, preclude a brand company from marketing an AG.[8] An AG is chemically identical to the branded drug, but sold as a generic product. Brand companies frequently launch AGs to compete with first-filer generics during Hatch-Waxman exclusivity. 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

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[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] 21 U.S.C. § 355(j)(5)(B)(iv).

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

prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand's agreement not to launch an AG.

A no-AG commitment can take a variety of forms. In some cases, the brand company explicitly agrees not to compete during the generic's exclusivity period. In other cases, the brand company grants the first-filer generic the exclusive rights to market a generic product, or designates the first-filer generic as the exclusive distributor of the brand's AG. Regardless of its form, however, the practical effect of the no-AG commitment is always to eliminate competition between the brand's AG product and the first-filer generic's product during the marketing exclusivity period and results in higher drug prices for consumers.

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 analysis 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."[9] As reflected in the FTC's 2011 AG Report, the economic realities of a no-AG commitment are that it provides significant value to a first-filer generic company and is now "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."[10]

A. Facing an AG Destroys a Significant Amount of the Value that a Generic Company Otherwise Would Obtain from Its 180-day Marketing Exclusivity

In its 2011 report on AGs, the FTC analyzed documents and empirical data covering more than a hundred companies and found that "the presence of authorized generic competition

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[9] *In re K-Dur Antitrust Litig.*, — F.3d —, No. 10-2077, 2012 WL 2877662, at *16 (3d Cir. July 16, 2012).

[10] AG Report, *supra* note 5, at i.

reduces the first-filer generic's revenues by 40 to 52 percent, on average" during the 180-day exclusivity period.[11] 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[12] and (2) wholesale and retail prices decrease when the first filer faces an AG.[13] For the first-filer generic of a $2.4 billion branded product, like Effexor XR, the difference between selling the only generic product during the exclusivity period and competing against an AG likely amounts to hundreds of millions of dollars.[14]

These economic realities are well known in the pharmaceutical industry, and the FTC's AG Report cites numerous documents from industry participants confirming the effects of no-AG commitments.[15] 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."[16]

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[11] *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).

[12] *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* Fed. Trade Comm'n, *Authorized Generics: An Interim Report* 3 (June 2009), *available at* http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.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").

[13] AG Report, *supra* note 5, at 41–48.

[14] *See, e.g.*, *id.* at 80; *see also infra* note 20 and accompanying text.

[15] 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).

[16] AG Report, *supra* note 5, at 81.

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 the 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.[17]

These examples demonstrate the significant financial ramifications that a brand company's AG can have on the first-filer generic company.

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 generic 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."[18] This commitment, therefore, is highly valuable to the first-filer generic. As the FTC's AG report reflects, with a no-AG commitment, "the first-filer's revenue will approximately double"[19] during the 180-day exclusivity period, compared to what the first filer would make if it competed against an AG. To put this impact in real dollars, Apotex's experience facing an AG version of Paxil is instructive. The U.S. sales of

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[17] Comment of Apotex Corp. in Support of Citizen Petition of Mylan Pharmaceuticals, 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.

[18] *See* Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study*, at 5 (2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[19] AG Report, *supra* note 5, at vi.

Paxil were roughly equivalent to those of Effexor XR in the year before each product faced generic competition ($2.31 billion and $2.39 billion, respectively).[20] Apotex estimates that it would have earned approximately $400 million more absent the AG. Thus, Wyeth's agreement not to launch an AG version of Effexor XR during Teva's first-filer exclusivity period may have increased Teva's revenues during that exclusivity period by $400 million dollars or more.

Teva itself acknowledged the economic realities of a no-AG commitment in its 2011 annual report filed with the Securities and Exchange Commission. According to Teva, its generic Effexor XR 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 are the only company authorized to sell during the 180-day period of exclusivity in 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 2010 operating results included contributions from products launched with U.S. market exclusivity, or with otherwise limited competition, such as venlafaxine [generic Effexor XR].[21]

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

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[20] *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; *2009 Top 200 Branded Drugs by Retail Dollars*, DRUG TOPICS (June 17, 2010), http://drugtopics.modernmedicine.com/drugtopics/data/articlestandard/drugtopics/252010/674961/article.pdf.

[21] *See* Teva Pharm. Indus. Ltd., Annual Report (Form 20-F), at 7 (Feb. 15, 2011) (also noting that "[e]ven after the exclusivity period ends, we frequently benefit from the continuing effect of being the first generic in the market"); *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).

C. In Light of These Economic Realities, a No-AG Commitment Is Without a Doubt a Method of Paying a Generic Company for Delayed Entry

Despite the clear financial benefits of a no-AG commitment to a first-filer generic company, Defendants argue that the Third Circuit's recent *K-Dur* decision should be limited to "overt cash payments."[22] Under Defendants' narrow reading, the Third Circuit's rule would apply to a brand company's payment of $400 million in cash to a generic patent challenger, but not to a transfer of $400 million worth of its stock. 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."[23]

Indeed, the economic realities of no-AG commitments mandate that such promises are analyzed like other forms of compensation paid to generics. That is because a no-AG commitment has the same capacity to purchase delay as an "overt cash payment." When a brand competes through an AG, it takes 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 in return for 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

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[22] Letter Br. from Liza M. Walsh to Judge Joel A. Pisano, No. 11-05479, Doc. No. 168 (filed Aug. 3, 2012), at 2.

[23] *In re K-Dur Antitrust Litig.*, — F.3d —, No. 10-2077, 2012 WL 2877662, at *16 (3d Cir. July 16, 2012) (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).

> delay its entry in exchange for that agreement, the combined net present value of both companies' products would be maximized.[24]

Because no-AG commitments are mutually beneficial, they have become a common form of compensation to generics. The FTC's recent reports on pharmaceutical patent settlements show that more than half of the payments from brand companies to first-filer generics involved no-AG commitments.[25]

Given the proliferation of these non-cash payments, accepting Defendants' argument that *K-Dur* is limited to overt cash payments would effectively nullify the Third Circuit's decision and permit anticompetitive settlements to proceed unchecked. 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" in an effort to evade antitrust scrutiny.[26] Another academic analysis acknowledged this shift and suggested that "this process of continuing evolution threatens the ability of existing antitrust institutions, particularly courts, to keep pace."[27] Allowing pharmaceutical companies to sidestep the *K-Dur* rule by simply making non-cash payments would elevate form over substance, in

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[24] AG Report, *supra* note 5, at 142 (summarizing a brand company's ordinary course document submitted to the FTC as part of its study of AGs).

[25] *See id.* 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.").

[26] 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.")

[27] C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 685 (2009).

direct contravention to 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."[28]

IV. The Federal Trade Commission Has Not Condoned No-AG Commitments

In addition to claiming that a "no AG" commitment cannot be a reverse payment, Defendant Teva asserts that its proposed rule is "in line with the Federal Trade Commission's adjudicative treatment of similar exclusive early-entry licenses," citing a 2004 FTC advisory opinion.[29] In fact, however, Teva knows full well that this FTC advisory opinion does ***not*** involve an exclusive license, or any other form of no-AG commitment; the license addressed in this advisory opinion was granted to Teva. Unlike the exclusive license at issue in this case, a non-exclusive license does not prevent competition from a brand AG and so does not have the same capacity to compensate the generic company for agreeing to a later entry date than it otherwise would accept. A non-exclusive license that conveys to the generic company only the right to enter and compete, by its very nature, does not involve the sharing of benefits that comes from eliminating competition. On the other hand, an exclusive license that precludes the brand company from competing with an AG for a specified period of time provides significant additional value to the generic company, derived from avoiding competition. The Third Circuit opinion reflects this critical distinction.[30] The same reasoning underlies the FTC reports cited in

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[28] *In re K-Dur Antitrust Litig.*, — F.3d —, No. 10-2077, 2012 WL 2877662, at *16 (3d Cir. July 16, 2012).

[29] *See* Reply Mem. in Support of Teva Defs.' Motion to Dismiss All Direct Purchaser Compls., No. 11-05479, Doc. No. 166 (filed Aug. 3, 2012), at 11, Ex. A.

[30] *See K-Dur*, 2012 WL 2877662, at *15 ("[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: the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand manufacturer to the generic challenger").

this amicus brief, which consistently distinguish non-exclusive licenses from exclusive licenses and other types of no-AG commitments.

Further, Wyeth's suggestion that the Court should draw any inference from the FTC's non-action on its mandatory MMA filing[31] is entirely without merit. The MMA is a notice-only statute: the FTC neither approves nor denies any filed agreement.[32] In any event, agency non-action on a matter, which may reflect resource constraints, the exercise of prosecutorial discretion, or other considerations, is not tantamount to approval of the underlying conduct.[33]

Teva and Wyeth are well aware that one need only read the first page of the FTC's AG Report to ascertain the Commission's position regarding no-AG commitments. It plainly states: "promises not to compete with generic entrants by marketing an AG are a common form of compensation to generics . . . and the competitive effects of such promises should therefore be analyzed in the same manner as other forms of consideration paid to generics."[34]

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

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[31] *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).

[32] *See, e.g.*, *Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, http://www.ftc.gov/os/2004/01/050210pharmrulesfaqsection.pdf (last visited Aug. 9, 2012).

[33] *See generally* MMA, *supra* note 31, at § 1117 ("[A]ny failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law . . . . ").

[34] AG Report, *supra* note 5, at i.

FTC would be pleased to address any questions the Court may have, including by participation at any hearing, should the Court find it useful.

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Respectfully submitted,

/s/ Timothy J. Slattery

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