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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,

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 a 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

pharmaceutical industry has long understood that a no-AG commitment is undoubtedly a payment, providing a convenient method for brand 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]

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."

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 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 benefit 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* 5 (2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.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

K-Dur presumption of illegality.[26] Under such a license, the revenues generated by the generic company derive entirely from the generic's marketability 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 profits from the additional delay in generic entry, while the generic company benefits by 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 profit 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

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 label 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.").

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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 payments 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

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.

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Respectfully submitted,

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