Legal Backgrounder

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FTC AND PATENT SETTLEMENTS:
AGENCY'S ANTITRUST CRUSADE EXPANDS UNSUCCESSFULLY

by
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The Federal Trade Commission (FTC) recently took the unusual step of submitting *amicus* briefs in two federal district courts, opposing dismissal of private antitrust claims arising from patent settlements. Those claims rely heavily on the U.S. Court of Appeals for the Third Circuit's 2012 decision in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), which declared settlements of pharmaceutical patent litigation under the Hatch-Waxman Act presumptively anticompetitive if they include "reverse payments" to the generic patent challenger. The Third Circuit thus broke with three other circuits, which had rejected similar antitrust challenges as long as the settlements excluded no more competition than did the patent itself.

But while *K-Dur* rejected the majority "scope of the patent" test, it limited its own holding, cautioning that "the only settlements subject to antitrust scrutiny are those involving a reverse payment." 686 F.3d at 217-18. This suggestion that courts should apply different antitrust rules to cash payments than to other types of settlement consideration was once the mainstay of the FTC's attack on Hatch-Waxman settlements. Now, however, the FTC briefs argue that the term "reverse payments" should be construed to include other forms of consideration not involving payments at all, such as granting a generic an exclusive license to sell the patented drug.

The FTC has fared poorly. One court refused to accept the FTC's brief, reasoning that the FTC was too biased to be a genuine friend of the court. The other accepted the brief, but rejected its thesis, dismissing the antitrust complaint because of the *K-Dur* limitation. A brief look at why the FTC has changed its view — why it is now asking courts to swallow only the hook and line of its argument, but not the sinker — tells us much about the breadth of its crusade against Hatch-Waxman settlements, and may prove important when the U.S. Supreme Court first speaks on this subject later this year in *FTC v. Actavis*.

FTC: "When We Said Money Was Different, Who Knew You Would Believe Us?"

In the FTC's first full opinion regarding "reverse-payment" settlements, it specifically concluded that money made the difference for liability. "A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent.… [T]he payment of money by Schering … is what makes this case different." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 987 (F.T.C. 2003), *rev'd sub nom. Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

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The FTC reiterated this position several times before Congress: "All settlements include some form of consideration flowing between the parties; *it is the type of consideration that matters* in the antitrust analysis. Some types of consideration, such as an early entry date, a royalty to the patent-holder, or compromising on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition." *Paying Off Generics to Prevent Competition with Brand Name Drugs: Hearing Before the S. Judiciary Comm.* 110th Cong. 132 (2007) (emphasis added). The academic commentators cited by the FTC emphasized that all other forms of settlement consideration were presumptively permissible. *E.g.*, Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, 17 ANTITRUST 70, 72 (Summer 2003) ("We may reasonably infer that the [other] terms of the settlement, e.g., the royalty rate paid or the field of use restrictions applied, reflect the assessments of the parties regarding their prospects in the patent litigation.").

How is money different? The FTC first assumed that all patent litigation could be settled with an "ideal" entry date if the parties negotiated on no other term but the time of entry. They then assumed that any additional payment to the generic was designed to postpone "the generic entry date which the parties *would otherwise have agreed to*." *Schering-Plough*, 136 F.T.C. at 993 (emphasis added). Thus, the payment was illegal because it "delayed generic entry beyond the date that *would have been provided* in a differently crafted settlement." *Id*. at 994. Courts quickly saw that this argument not only assumed away the controlling issue (*i.e.*, the patentee's right to exclude infringing drugs), but was wrong on its own terms.

First, the assumption that parties should negotiate along only one axis — an approved entry date — is unfounded factually and legally. Factually, the parties do not value the length of any proposed license in the same way. *See* Mark G. Schildkraut, *Patent Splitting Settlements and The Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1067 (2004). Because generics charge lower prices, they make less profit for each period of sales than innovators lose for the same period. Suppose the parties are only $10 million apart in negotiations; if the generic needs six more months to generate that much profit, but those six months will cost the innovator $30 million, no settlement will happen. In such a case, a $10 million payment bridging that gap does not shorten the license; it makes the license possible.

Legally, moreover, it is irrelevant that a longer license might have allowed "more" competition than the license actually granted. One can always imagine a more competitive bargain than the one actually struck. *See Verizon Commc'ns. Inc. v. Trinko*, 549 U.S. 398, 415-16 (2004) (conduct is not illegal just because "some other approach might yield greater competition").

Courts rejecting these claims saw that, whatever theory of harm the FTC invoked, payments did not matter. All patent litigation seeks to "delay" infringing competition, and all patent licenses — with or without payments — divide markets among rivals if you ignore the patent. XII Herbert Hovenkamp et al., ANTITRUST LAW ¶ 2040b (1999) ("[Licensing] agreements would generally be classified either as per se unlawful naked price fixing, or as per se unlawful naked horizontal market divisions" in the "absence of a patent." (footnote omitted)).

All settlements, moreover, *must* involve mutual consideration in order to form a valid contract. Obviously, the generic "would not settle unless he had something to show for [it]." *Asahi Glass Co. v. Pentech Pharms. Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.). When the patentee compromises on damages, for example, that is an implicit payment to the infringer indistinguishable from a cash payment. Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements*, 15 FED. CIR. B.J. 617, 621 (2005). The Hatch-Waxman process, moreover, frees generics from exposure to damages by allowing them to challenge the patent before making infringing sales. That makes cash consideration more efficient, but does not change the fact that mutual consideration occurs in every case. *Id.* ("Hatch-Waxman creates a context in which payments … become explicit rather than implicit, but it does not change the

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underlying nature of the payments or make them more anti-competitive ….").

The late Judge David Trager saw clearly that the FTC's theory of harm could result from any royalty-bearing license. The argument thus proved too much: "If the settlement with a payment to a generic is to be [illegal], even though [within] the scope of the patent, … the next antitrust challenge … might well take place in the context of a license with royalty, a result that even Professor Shapiro would presumably disfavor." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 533 (E.D.N.Y. 2005).

Following these defeats and several others, *e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005), it may seem odd that the FTC would now advance the very argument used to defeat it previously. The FTC admits that its current theory would ban any settlement in which generics receive "value," but claims that this is a boon, because all such settlements contain "reverse payments." We attribute the FTC's current tack to three causes. First, because the FTC will subject settling parties who use cash to a lengthy and expensive investigation, actual payments in Hatch-Waxman settlements have essentially disappeared. Second, the FTC decided to seek the result denied it by the courts from Congress, through new legislation. Finally, the FTC also decided that it dislikes exclusive patent licenses for generic drugs. For the Commission, all of these developments required an expanded definition of "payments."

When Payments Became 'Compensation' and Compensation Became 'Value'

The first legislative proposal to ban reverse payments followed fast on the heels of the FTC's defeat in *Schering-Plough*. *See* The Preserve Access to Affordable Generics Act, S. 3582 (June 27, 2006). Merely drafting the bill, however, put the lie to the FTC's notion that "it is the type of consideration that matters." Rather, the bill prohibited all settlements where the generic "receives anything of value." *Id.*, § 2. But all consideration, including the early-entry license that the FTC favors, is something "of value." To avoid criminalizing all settlements, the bill carved an exception where "the value paid by the NDA holder to the ANDA filer … includes no more than the right to market the ANDA product prior to the expiration of the patent." *Id.*

Pushing the bill through Congress, moreover, raised another problem. If actual cash payments were no longer happening, how could the FTC maintain its drumbeat of urgency for a statutory fix? It did so by issuing annual reports to Congress, breathlessly announcing that the number of Hatch-Waxman "reverse payment" settlements was not just increasing, but "skyrocket[ing]." *E.g.*, Press Release, *FTC Staff Report Finds 60 Percent Increase in Pharmaceutical Industry Deals* (May 3, 2011). How? This conclusion required redefining the word "payments" to mean "some form of compensation." FTC, *Summary of Agreements Filed in FY 2008*, at 1, n.2. When this new definition was adopted, the FTC had been studying the effect of generic drug entry by more than one authorized generic licensee. The FTC apparently concluded it did not want patent settlements to preclude additional authorized generic licensees, which would happen if the innovator made the settlement license wholly exclusive. Thus, the FTC added this example to its expanded definition of "payments": "For example, agreements with incentives for a branded drug company not to launch an authorized generic product could effectively compensate a generic company." *Id.*

Thus did the FTC marry its crusade against reverse payments with its policy to inhibit exclusive drug licenses — by defining the latter to be the former. But granting an exclusive license is one of the oldest and most legally secure rights of any patentee. The Supreme Court held over a century ago that antitrust does not prohibit "a restraint of commerce that may arise from reasonable and legal conditions imposed upon the … licensee of a patent." *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 92 (1902); *see United States v. Studiengesellschaft Kohle, m.b.H.*, 670

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F.2d 1122, 1129 (D.C. Cir. 1981) (no liability where the same exclusion "would have resulted from a conventional grant of an exclusive license"). Because the 2006 bill and others, *e.g.*, S. 316, 110th Cong. (2008); S. 269, 111th Cong. (2009), died without enactment, these established rules of patent and antitrust law have not yet been overturned. Nonetheless, the FTC's revised definition of payments gave it a new strategy for achieving the same result in court.

K-Dur *and Its Aftermath*

In 2012, the Third Circuit finally did embrace the FTC's claim that reverse payments are presumptively illegal. *K-Dur*, 686 F.3d 197. But, rather than supplying a competitive rationale for doing so, *K-Dur* simply swallowed the FTC's position whole — including its original contention that payments were (somehow) different: "We caution that our decision today is limited to reverse payments …." *Id.* at 216.

In its district court *amicus* briefs, the FTC attempted to sidestep that limitation by explaining that the term "reverse payments" means anything of value, including an exclusive license. In other words, the *K-Dur* limitation was no limitation at all. The FTC failed to explain why, if exclusive licenses are payments, favorable royalty rates, compromises on damages, or field-of-use restrictions are not payments as well. The FTC's view, if accepted, would have *K-Dur* presumptively outlaw all Hatch-Waxman settlements, because all necessarily provide consideration ("value") to the settling generic.

So far, the courts are unimpressed. One found the Commission too biased to act as an *amicus*. *Prof'l Drug Co. v. Wyeth Inc.*, 2012 WL 4794587, at *2 (D.N.J. Oct. 3, 2012) ("[T]he extent to which the FTC is partial to a particular outcome weighs against granting the agency's motion."). The other took the brief, but rejected its argument. It held that the limitation actually did have meaning, and refused to extend *K-Dur* to an exclusive license. *In Re Lamictal Direct Purchaser Antitrust Litig.*, 2012 WL 6725580, at *6 (D.N.J., Dec. 6, 2012) ("The Court finds that the term 'reverse payment' is not sufficiently broad to encompass any benefit … to [the generic] in a negotiated settlement.").

Conclusion

To be sure, *K-Dur*'s limitation of its rule to reverse payments makes little sense — but that is because *K-Dur*'s rule itself makes no sense: it would render cash settlements unlawful, while ignoring the only important question, *i.e.*, whether the allegedly excluded generic competition would have been legal. *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 363-64 (7th Cir. 1907) ("[T]he public [is] not entitled to profit by competition among infringers."). The Supreme Court stands poised to decide the issue by June when it reviews *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012). It will determine whether the *K-Dur* "presumptive illegality" or the majority "scope of the patent" rule is correct. In doing so, the Court should note the FTC's concession that its position abides no limiting principle: according to the Commission, all settlements that convey value — which means all of them — are presumptively illegal.

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