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The First Circuit Agrees that Non-Cash Reverse Payments Are Subject to Antitrust Scrutiny. Does the Loestrin Decision Point to Battles to Come?

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Recently, the First Circuit became the second federal appellate court interpreting the Supreme Court's landmark decision in *FTC v. Actavis, Inc.*[1] to hold that non-cash "reverse payments" between pioneer and generic pharmaceutical manufacturers risk antitrust liability. Like the Third Circuit in *King Drug*,[2] the First Circuit's decision in *In re Loestrin 24 FE Antitrust Litigation* held that a pioneer drug manufacturer's agreement not to market an authorized generic product during a generic challenger's 180-day exclusivity period to settle litigation under the Hatch-Waxman Act is subject to rule of reason scrutiny under the Sherman Act.[3] In reversing the District Court's holding that *Actavis* does not apply to non-cash reverse payments, *Loestrin* continues the trend towards expanded liability for settling parties. However, *Loestrin's* extensive discussion of the pleading standard applicable to *Actavis*' "large and unjustified payment" factor points toward future battles over the plausibility of complaints alleging non-cash reverse payments.

The dispute in *Loestrin* centers around Watson Pharmaceuticals, Inc.'s ("Watson") challenge to the validity of Warner Chilcott's ("Warner") patents covering the active ingredient of its drug, Loestrin 24 FE ("Loestrin"), an oral contraceptive, and Watson's plans to market its own generic version of Loestrin. To increase generic pharmaceutical competition, the Hatch-Waxman Act[4] (the "Act") provides generic manufacturers with unique incentives to challenge the patent protection accorded to pioneer drugs. Instead of requiring detailed studies demonstrating efficacy and safety, the Act permits generic challengers to "piggy-back" on the pioneer drug manufacturer's studies using an abbreviated new drug application (an "ANDA") so long as the generic challenger demonstrates bioequivalence.[5] And, most importantly, the FDA grants the first successful ANDA filer a 180-day exclusivity period during which time other generic challengers are not permitted to market the drug.[6] The 180-day exclusivity period can be extraordinarily valuable to the generic challenger. However, in order to market a generic drug, a generic challenger must first overcome the pioneer manufacturer's patent monopoly.

The most common form of Hatch-Waxman challenge is known as a Paragraph IV certification. Under Paragraph IV, the generic manufacturer certifies that the pioneer's patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug."[7] In almost all cases, a Paragraph IV certification provokes patent infringement litigation by the pioneer manufacturer because certification is an act of constructive infringement and the initiation of litigation triggers a 30-month stay of the FDA's consideration of the ANDA application.[8]

In *Loestrin*, Watson filed the first ANDA challenging Warner's patent on Loestrin and certified that its generic product did not infringe the patent and/or the patent was invalid under Paragraph IV.[9] In January 2009, after Warner filed an infringement suit against Watson, the parties entered into a settlement agreement wherein Watson was permitted to market generic Loestrin beginning in January 2014 and Warner agreed not to market an authorized generic Loestrin product during Watson's 180-day exclusivity period.[10] The agreement also provided fees to Watson for the co-promotion of another drug and rights to sell a third, Warner brand-name drug that was in clinical development.[11]

A group of direct purchasers and end purchasers filed complaints alleging that Warner's agreement not to market an authorized generic during Watson's exclusivity period constituted an illegal reverse payment under Section 1 of the Sherman Act.[12] Although *Actavis* had already been decided at the time it reached its decision, in dismissing the purchasers' complaints, the District Court held that non-cash reverse payments, including no authorized generic agreements, are not subject to antitrust scrutiny under *Actavis*.[13] The District Court explained: "Reading *Actavis*, this Court cannot help but find that it applies solely to monetary settlements; the narrowness of the Supreme Court's language and the cash-focused guidance for applying the rule of reason permit no other conclusion until and unless the Supreme Court expands its holding."[14] In dismissing the complaints, the District Court further relied on *Actavis*'guidance that a "large and unjustified" payment to the purported generic infringer may serve as a proxy for an agreement to maintain supracompetitive prices and "requires, on the part of the plaintiff, and ultimately the reviewing court (or jury), an ability to assess or calculate the true value of the payment made by the patentee to the generic competitor."[15] Unlike a cash settlement, the District Court held that "a non-cash settlement, particularly one that is multifaceted and complex…is almost impossible to measure against these [] factors."[16] Accordingly, the District Court held that *Actavis* could not be applied to non-monetary settlements and dismissed the plaintiffs' complaints.

Rejecting the District Court's reasoning, the First Circuit held that *Actavis* applies to non-monetary reverse payments because "the key word used throughout the opinion is 'payment,' which connotes a much broader category of consideration than cash alone." [17] Notwithstanding, the *Loestrin* Court agreed that, under *Actavis*, "the size of the reverse payment, particularly as it relates to potential litigation expenses, is central to the antitrust query and requires that the reviewing court or factfinder [sic] assess the value of the payment."[18] The Circuit parted ways with the District Court, however, based on *Actavis*' repeated references to the size of the alleged reverse payment which, in the Circuit Court's view,presupposed that the size of the *payment* in question – whatever formit takes – is ascertainable.[19] Accordingly, the First Circuit explained that "[a]lthough the value of non-cash reverse payments may be much more difficult to compute than that of their cash counterparts, antitrust litigation often requires an 'elaborate inquiry into the reasonableness of a challenged business practice' and, as a result, is 'extensive and complex.'"[20] Stopping short of endorsing a heightening pleading standard, the court held that plaintiffs must "'estimate the value of the term, at least to the extent of determining whether it is large and unjustified.'"[21] Because the District Court did not assess the size of the alleged reverse payment at issue, the Circuit Court remanded the case for further proceedings.

In addition to expanding reverse payment liability to non-cash reverse payments in the First Circuit, *Loestrin* confirms that new battle lines are being drawn in reverse payment litigation. Specifically, it appears that plaintiffs' attempts to adequately plead "large and unjustified" non-cash payments will assume greater importance and defendants' challenges to the sufficiency of such pleadings will grow in intensity. Under *Iqbal* and *Twombly*, a plaintiff must "state a claim to relief that is plausible on its face" by alleging non-conclusory "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."[22] Although *Loestrin* holds that a plaintiff need only estimate whether the payment is large and unjustified at the pleading stage, the plausibility of such allegations are context-specific, and they must be supported by non-conclusory factual content. On remand and in the cases that follow *Loestrin*, litigants' ability to meet this standard will be tested.

[1] 133 S. Ct. 2223 (2013).

[2] *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

[3] *Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co. (In re Loestrin 24 FE Antirust Litig.)*, 2016 U.S. App. LEXIS 3049, at *28 (1st Cir. Feb. 22, 2016).

[4] 21 U.S.C. § 355, *et seq*.

[5] 21 U.S.C. § 355(j).

[6] 21 U.S.C. § 355(j)(5)(B)(iii), (iv).

[7] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[8] 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(j)(5)(B)(iii).

[9] *Loestrin*, 2016 U.S. App. LEXIS 3049, at *15.

[10] *Id.* at *15-16.

[11] *Id.* at *16-17.

[12] 15 U.S.C. § 1.

[13] *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180, 192 (D.R.I. 2014)).

[14] *Id.*

[15] *Id.* at *190.

[16] *Id.* at *191.

[17] *Loestrin*, 2016 U.S. App. LEXIS 3049, at *27.

[18] *Id.* at *30.

[19] *Id.* at *31.

[20] *Id.* at *32 (citation omitted).

[21] *Id.* at *32-33 (*quoting In re Actos End Payor Antitrust Litig.*, 2015 U.S. Dist. LEXIS 127748, at *43, 2015 WL 5610752, at *13) (S.D.N.Y. Sep. 22, 2015). Importantly, the *Loestrin* Court also held that the five-factor analysis utilized by the Supreme Court in *Actavis*, which includes "large and unjustified" payments, does "not overhaul the rule of reason, nor should they [sic] create a new five-part framework in antitrust cases." *Loestrin*, 2016 U.S. App. LEXIS 3049, at *30 n.12.

[22] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007).

Author of this alert: *Andrew S. Wellin, Associate*.

Related Professionals

- **John R. Ingrassia**
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- **Colin Kass**
  Partner
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  Partner