What's At Stake In Bystolic 'Side Deals' Litigation

By **Ted Mathias, Caroline Boisvert and Logan Morris** (November 21, 2023)

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Antitrust litigation around reverse payment settlements of patent litigation has exploded since the U.S. Supreme Court's 2013 decision in Federal Trade Commission v. Actavis Inc.[1]

A decision from the U.S. District Court for the Southern District of New York last year is now on appeal to the U.S. Court of Appeals for the Second Circuit and, if affirmed, would likely create a circuit split in pleading standards for reverse payment cases.

Ahead of the Dec. 6 oral argument in In re: Bystolic Antitrust Litigation,[2] we preview the key issues in a case that is almost certain to yield a cert petition and could profoundly affect reverse payment cases for years to come.

Reverse Payments Explained

In a reverse payment settlement, the patentee pays the accused infringer cash or other consideration to end the litigation. The payment is considered reverse because in ordinary patent litigation, the accused infringer will settle by paying the patentee. It is the patentee, after all, that is seeking damages for the alleged infringement.

The dynamic is different in the pharmaceutical sector. Legislation controlling the entry of generic pharmaceuticals and biosimilars provides for preentry litigation where originators — those who bring new drugs to market — assert patents to prevent competitors from launching generic versions of the drug.[3]

Because there has been no market entry, ordinarily there is no claim for damages. Further, the originator typically possesses some level of market power before generic entry and can profitably price its drug at supracompetitive levels.

Antitrust plaintiffs assert that the originator can unduly maintain its market power by paying the generic to stay off of the market for longer than the originator's patents might warrant.

The losers in that scenario are consumers, who pay supracompetitive prices for longer than they would have if, at least in theory, the generic had held out for an earlier entry date as part of the settlement instead of accepting the reverse payment.

The Supreme Court Gives Life to Reverse Payment Challenges

In Actavis, the Supreme Court addressed the legal standard that applies to antitrust cases challenging reverse payments under Section 1 of the Sherman Act.

It rejected the U.S. Court of Appeals for the Eleventh Circuit's scope-of-the-patent test providing "that a reverse payment settlement agreement generally is 'immune from

antitrust attack so long as its anti-competitive effects fall within the scope of the exclusionary potential of the patent.'"[4]

The court held that large and unjustified reverse payments were subject to traditional rule-of-reason antitrust analysis and thus opened the door to antitrust claims by purchasers — and classes of purchasers — who allegedly had to pay more for the drugs because of an anti-competitive settlement.[5]

Pleading Standards for Reverse Payment Challenges

The Supreme Court expressly left the structuring of these antitrust cases to lower courts.[6] Much of the case law following Actavis, including Bystolic, has focused on pleading standards.

Under Bell Atlantic Corp. v. Twombly, the alleged facts must "be enough to raise a right to relief above the speculative level[.]"[7] Therefore, the factual allegations must permit a "plausible" inference of an anti-competitive reverse payment.[8]

Courts have wrestled with what constitutes a plausibly alleged reverse payment that, as set out in Actavis, is large and unjustified.

For example, not long after the Actavis decision, in In re: Lipitor Antitrust Litigation, the U.S. District Court for the District of New Jersey granted a motion to dismiss based on the "large" requirement because the "[p]laintiffs failed to plausibly allege an estimate of the monetary value of the non-monetary payment[.]"[9]

The U.S. Court of Appeals for the Third Circuit reversed, holding that requiring a reliable monetary estimate of noncash payments was premature and that "more detailed, advanced calculations ... may come later."[10]

The U.S. Court of Appeals for the First Circuit similarly explained in In re: Loestrin 24 Fe Antitrust Litigation that requiring "precise figures and calculations ... would impose a nearly insurmountable bar for plaintiffs at the pleading stage."[11]

On the issue of whether the payment is unjustified, the Third Circuit again has set a relatively low bar. "[Plaintiffs] need only allege the absence of a 'convincing justification' for the payment."[12] They do not need "to come up with possible explanations for the reverse payment and then rebut those explanations in response to a motion to dismiss."[13]

To be sure, specific facts are still required.[14] In Lipitor, the plaintiffs properly alleged that actual saved litigation costs "fail[ed] to explain the hundreds of millions of dollars of liability released by Pfizer."[15]

In FTC v. AbbVie in the Third Circuit in 2020, the plaintiff properly alleged that AbbVie Inc.'s side agreement was unjustified because it accelerated generic entry and provided unusually unfavorable royalty terms on another AbbVie drug.[16]

The lone instance where a court of appeals has affirmed a district court's dismissal of a claim under Actavis on a motion to dismiss is of limited precedential value because the case turned on very specific facts.

The plaintiffs in Mayor of Baltimore v. AbbVie alleged that "AbbVie gifted the biosimilar makers with 4+ years of profits in Europe, in exchange for their agreement not to enter the

U.S. market until 2023."[17]

But three of the settling biosimilar sponsors did not plan to sell their product in Europe and still accepted a U.S. entry date of 2023, "mak[ing] it hard to see [the] 2023 [entry date] as a delay that AbbVie 'bought' by concessions made in Europe."[18]

As of the promised entry date in Europe, AbbVie only had patents covering three of the biologic's nine approved indications, making biosimilar entry in 2018 "inevitable."[19]

And, there was no payment or other exchange of value beyond the promised pre-expiration entry dates. Given these holes in the plaintiffs' theory, the court held that it was "too speculative to treat the different entry dates [in the U.S. and Europe] as some kind of 'reverse payment' rather than a normal response to a different distribution of legal rights under different patent systems."[20]

An Important Test Case

Bystolic stands in stark contrast to Mayor of Baltimore because the case is rife with "exchanges of value."

The originator, Forest Laboratories, settled with six companies seeking to market generic versions of Bystolic, a treatment for high blood pressure. The six companies agreed not to launch their generics until three months remained in the term of Forest's latest-expiring patent.

But more importantly, Forest entered into contemporaneous side deals with each generic. Side deals in this context are business arrangements whereby the originator provides some value to a settling generic, typically a cash payment in exchange for goods or services.

Antitrust plaintiffs and the FTC have long argued that side deals often conceal a quid pro quo where the originator, by overcompensating the generic for a good or service, is actually paying the generic to stay off of the market for a longer period of time.

As an example of a side deal in Bystolic, Forest agreed to buy patents covering the manufacture of nebivolol, the active ingredient in Bystolic, from one of the settling generics. The plaintiffs allege that the patent purchase was unnecessary because Forest had long made and sold nebivolol without licensing those patents. The defendants responded that the patent purchase enabled Forest to develop a new nebivolol product called Byvalson.

The district court held that the plaintiffs failed to plausibly allege that this and the other five side deals were unjustified reverse payments. Over two opinions totaling 117 pages, the court examined both the terms of the agreements and the plaintiffs' more general allegations that, for example, commercial arrangements between originators and generics are unusual and that Forest has a track record of using side deals.[21] It concluded that the plaintiffs' claims lacked plausibility.[22]

On appeal, the plaintiffs argue that the district court erred by offering its own pro-competitive justifications for the side deals and faulting the plaintiffs for not countering those justifications.

They also point to repeated instances where the district court appeared to weigh competing inferences and conclude that inferences adverse to the plaintiffs' claims were more plausible.[23]

That analysis would seem to run afoul of Second Circuit case law holding that dismissal of a complaint is improper "merely because the court finds a different version [of the events] more plausible."[24]

The defendants have responded that the plaintiffs' "hoped-for inferences" are inconsistent with the actual provisions of the settlement agreements incorporated into the plaintiffs' complaints.

They also maintain that Actavis turned on allegations that the originator paid the generics up to 10 times the amount that it had paid for similar services and thus rendered plausible the FTC's allegation that the payment was "in return for staying out of the market."[25] Mere allegations that the side deals' value exceeds the litigation costs the originator saved by settling are, for the defendants, insufficient to state a claim.

An affirmance would appear to put the Second Circuit on a collision course with the Third Circuit. The Third Circuit has stated that "[t]o plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a 'convincing justification' for the payment."[26]

The plaintiffs in Bystolic have pointed to an array of facts that they say indicate the side deals were pretextual. Oral argument will offer significant clues as to whether the Second Circuit panel views the Supreme Court's holding in Actavis as limited by the factual allegations specific to the FTC's complaint.

Oral argument listeners should also be attentive to how the panel approaches side deals. The plaintiffs assert that side deals are inherently suspect because they can disguise an unjustified reverse payment.

For defendants, so-called side deals are just garden-variety commercial agreements that should be looked at no differently in antitrust terms than an agreement between an originator and a contract research and development firm that works with the originator on some aspect of drug development.

Certainly, when sophisticated parties talk settlement, they frequently look beyond the dispute's four corners in search of arrangements that deliver value to both sides.

Regardless of where the Second Circuit lands, a cert petition to the Supreme Court seems almost certain.

The FTC has filed an amicus brief urging reversal and received permission to participate in the oral argument.[27] The prospect of continued FTC support would surely encourage plaintiffs to seek Supreme Court review if the Second Circuit affirms.

In the event of reversal, defendants would surely be supported by pharmaceutical industry groups seeking the Supreme Court's help in clarifying the boundaries of licit conduct and narrowing the number of claims that can survive into discovery.

And if the Supreme Court does not grant certiorari, the Second Circuit's decision will weigh heavily on patent litigants considering settlement and potential plaintiffs considering challenges to those settlements.

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Disclaimer: Axinn represented one of the Bystolic defendants in a related matter.

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[1] FTC v. Actavis Inc., 570 U.S. 136 (2013).

[2] In re Bystolic Antitrust Litigation, No. 23-410 (2d Cir. filed Mar. 20, 2023).

[3] We use the terms "pharmaceuticals" and "drugs" here to describe both traditional pharmaceuticals and biologics.

[4] Actavis, 570 U.S. at 141.

[5] See id. at 158-159.

[6] Id. at 160.

[7] Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

[8] In re Lipitor Antitrust Litig., 868 F.3d 231, 239 (3d Cir. 2017).

[9] In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 547 (D.N.J. 2014), rev'd and remanded, 868 F.3d 231 (3d Cir. 2017).

[10] Lipitor, 868 F.3d at 254-255.

[11] In re Loestrin 24 Fe Antitrust Litigation, 814 F.3d 538, 552 (1st Cir. 2016).

[12] Lipitor, 868 F.3d at 256 (quoting Actavis, 570 U.S. at 159).

[13] Id.

[14] See id. at 251-252.

[15] Id. at 256.

[16] FTC v. AbbVie Inc., 976 F.3d 327, 357 (3d Cir. 2020).

[17] Mayor & City Council of Baltimore v. AbbVie Inc., 42 F.4th 709, 714 (7th Cir. 2022).

[18] Id. at 715.

[19] Id.

[20] Id. at 716.

[21] In re Bystolic Antitrust Litig., No. 20-5735, 2023 WL 2656357 (S.D.N.Y. Feb. 21, 2023); In re Bystolic Antitrust Litig., No. 20-5735, 2022 WL 594534 (S.D.N.Y. Jan. 31, 2022).

[22] Bystolic, 2023 WL 2656357, at *10.

[23] Brief for Plaintiffs-Appellants at 2, In re Bystolic Antitrust Litig., No. 23-410 (2d Cir. Jun. 14, 2023), ECF No. 119.

[24] See, e.g., Anderson News LLC v. Am. Media Inc., 680 F.3d 162, 185 (2d Cir. 2012).

[25] Actavis, 570 U.S. at 154.

[26] Lipitor, 868 F.3d at 256.

[27] Three other amicus briefs were filed in support of affirmance.