How to Settle a Patent Case After Actavis

Presented by
Health Care & Pharmaceuticals Committee
ABA Section of Antitrust Law

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The Supreme Court rejected both the deferential “scope of the patent” test as well as the FTC’s proposed “quick look” rule of presumptive unlawfulness:

- “[T]he FTC must prove its case as in other rule-of-reason cases.”
  

- “[R]everse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws.”
  
  *Actavis*, 133 S. Ct. at 2227 (emphasis added).

- The majority opinion uses the word “sometimes” six times in its analysis.

- The Court repeatedly referred to “large and unjustified” payments as the competitive concern.
The FTC reports “a substantial decrease” in reverse payments

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"You appear to be suffering from the effects of secondhand litigation."
Unpacking the “substantial decrease”

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- Of the 29 “potential pay-for-delay” settlements
  - 14 include a payment solely for litigation expenses
  - 4 include “no-AG commitments”
  - 11 include “a side business deal” (i.e., just 8% of all final settlements)

- The FTC does not provide the breakdown for the 13 “potential pay-for-delay” settlements involving first filers

- FY2014 ended on September 30, 2014, but the FTC has not released that data yet
Safe harbors

- Innovator and generic can settle on any entry date within the patent term without concern as long as no “payment”
  - Conversely, if entry is immediate, parties can do any other business they wish

- Innovator can pay generic the innovator’s avoided litigation expenses
  - Readily justified at $4 million or more in many cases

- Parties can demonstrate independence of the settlement from business transactions by doing them at different times
  - E.g., enter settlement with no contingencies, then enter manufacturing deal 30 days later
Is there a “payment”?

- “Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” *Actavis*, 133 S. Ct. at 2236.

- This reasoning seems irreconcilable with the FTC’s take on *Actavis*:

  “*Actavis* thus reflects a two-part framework to assess whether a settlement agreement contains a reverse payment: (1) Is the alleged payment something that a generic challenger could not have obtained had it won the litigation? and (2) Are the parties sharing monopoly profits preserved by avoiding competition?”

"Probably some kind of out-of-court settlement, Alice."
Lower courts have diverged on what constitutes a “payment”


- In re Wellbutrin XL Antitrust Litig., No. 08-cv-2431, slip op. at 4 (E.D. Pa. Jan. 17, 2014) (“The Court is not prepared at this point to accept [the] argument that only a large cash payment from the patentee to the generic is subject to antitrust scrutiny under Actavis.”).


- United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc., No. 14-MD-02521, 2014 WL 6465235, at *12 (N.D. Cal. Nov. 17, 2014) (Lidoderm) (“I agree with the courts who have held that a no-authorized-generic term can constitute a payment.”).

But none of the lower court decisions thus far turn on the valuation of a side business deal.
"Your mother and I still think two dollars a week is plenty, but, in an effort to avoid litigation, we're willing to go to two seventy-five."
**Nexium** verdict did not turn on valuation of a side business deal

- **On December 5, 2014,** the jury found for defendants in the first reverse payment case to go to trial since Actavis. *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-MD-2409-WGY (D. Mass.).
  - The jury found a “large and unjustified” payment by the innovator to the generic
  - But the jury also found that there would not have been an earlier agreed entry date but for the payment, which disposed of the case (see Question 4 of special verdict form)
Demonstrating fair value

- **Actavis** basically puts things back where they were in 2002 during the FTC’s first “pay for delay” challenge: *FTC v. Schering-Plough and Upsher-Smith*. *In re Schering-Plough Corp.*, No. 9297, 2002 WL 1488085 (F.T.C. June 27, 2002).

  - Still the only trial ever to turn on the valuation of a so-called settlement “side deal”
  
  - Defendants won 40-day trial before the FTC’s own ALJ
Lessons from *Schering-Plough/Upsher-Smith*

- Schering and Upsher-Smith settled on the eve of trial, agreeing to a generic entry date prior to patent expiration.

- Schering agreed to pay $60mm over 3 years to in-license a potassium chloride cholesterol treatment from Upsher-Smith.
  - Potassium chloride products were struggling at the time and the FTC alleged the IP license was essentially worthless.

- Defendants proved during the 40-day trial that there were two separate teams within Schering that independently determined the agreed generic entry date and the value of the IP license.
  - FTC’s ALJ found there was no antitrust violation under the rule of reason.

(N.B. Potassium chloride turned out to be a successful and lucrative therapy, confirming the value of the IP license.)
Potential tools available to settling parties

- Contemporaneous evidence of fair market value
  - Comparable transactions
  - Third-party valuation opinions
  - Firewall separating negotiators of settlement entry date from negotiators of contemporaneous business transactions
- Fact findings on settlement from the patent judge
  - Findings on uncertainty of patent case and expense entailed for final adjudication, which can substantiate innovator’s avoided litigation expense
  - Evidentiary hearing on the fair market value of any payment
- Consent decree from the patent judge blessing the settlement and any contemporaneous business transactions
Stand-alone profitability of a “side deal” to the innovator as a safe harbor under *Actavis*?

- *Actavis* held that the “payment may reflect compensation for other services that the generic has promised to perform . . . .” *Actavis*, 133 S. Ct. at 2236.
  - If the innovator pays the generic $1 for co-promotion services and makes $1.10 from those services, the conduct is not diseconomic

- *Actavis*’s repeated emphasis on “large and unexplained” payments means that from such diseconomic conduct, courts can infer the payment was for delay
  - Without such diseconomy, there can be no such inference
  - There’s nothing “unexplained” about entering into a profitable transaction
Stand-alone profitability as a safe harbor

- For example, there is an absolute safe harbor for above-cost pricing against claims of predatory pricing. See *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223-24 (1993).

  - *Brooke Group* acknowledges that above-cost pricing can still potentially have some anti-competitive effect, but deems that problem irremediable by antitrust because courts are ill-suited to price setting

- This same logic is applicable under *Actavis*’s guidance that a payment contemporaneous with settlement permissibly “may reflect compensation for other services that the generic has promised to perform . . . .” *Actavis*, 133 S. Ct. at 2236.

  - In *Actavis*, which addressed dismissal under Rule 12(b)(6), the Court assumed the truth of the FTC’s allegation that “the other services had little value.” *Id.* at 2229.
“You can’t please all the people all the time, so you might as well please the pharmaceutical lobby.”
Actavis is more about the past than the future of the pharma industry

- Parties settle patent litigation for a range of complex, subjective reasons, including risk aversion, availability of other opportunities, and other strategic objectives.

- Just as reverse payments evolved as parties’ economic response to the asymmetrical risk problems of Hatch-Waxman litigation, parties will be equally creative in responding to Actavis.
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