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The Future of Hatch-Waxman Settlements After *Actavis*

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July 2013

Background: Paragraph IV Entry

The Hatch-Waxman Act provides, *inter alia*:

- An ANDA first filer who makes a paragraph IV certification that patents listed in the Orange Book for a brand drug are invalid or not infringed may earn early market entry and a 180-day exclusive marketing period if:
  - no timely patent infringement suit is filed;
  - a court upholds the patent challenge; or
  - the suit is settled.

Background: Hatch-Waxman Patent Suits

- A brand manufacturer (“brand”) obtains an automatic 30-month stay of FDA approval of the challenger’s generic if the brand files a patent infringement suit within 45-days of notice of the paragraph IV certification.

- Once the automatic 30-month stay ends, provided FDA approval is given, the generic maker may take steps including:
  - “launching at risk”; or
  - avoiding the risk of treble damages by foregoing entry and continuing the patent suit.

Background: Hatch-Waxman Settlements

- Hatch-Waxman patent suits have often been resolved by what the FTC has labeled "reverse payment" or "pay for delay" settlements, which may include the following provisions, among others:
  - an entry date for the sale of the generic before the expiry of the brand's patents; and
  - a cash payment to the generic challenger.

Background: Traditional Antitrust Analysis

Agreements entered between actual or potential competitors in the same market have typically been treated by the courts:

- as illegal "per se;" or
- as subject to a rule of reason analysis.

Background: Per Se Antitrust Violations

- Per se liability is limited to agreements between competitors that are "so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality." *Texaco, Inc. v. Dagher*, 547 U.S. 1, 5 (2006).

- Such per se antitrust violations include price-fixing and market division agreements.

Background: Rule of Reason Analysis

- A rule of reason analysis initially requires showing that an adverse effect on competition was proximately caused by the alleged trade restraint in a relevant product market.

- A demonstrated adverse competitive effect may be justified by showing offsetting pro-competitive effects flowing from the alleged restraint.

- This balancing between the demonstrated adverse effect and any pro-competitive effects involves a factually complex, case-by-case analysis. Consequently, private litigants often have been reluctant, in the past, to pursue rule of reason antitrust cases because of their length, uncertainty, and litigation costs.

The Circuit Split As to Applicability of Antitrust Laws to Hatch-Waxman Settlements

- A decade ago, the Sixth Circuit held:
  - A Hatch-Waxman settlement in which a payment for forty-million dollars was made to a generic maker was “a classic example of a per se illegal restraint of trade.” *In re Cardizem CD Antitrust Litig*., 332 F.3d 896, 908 (6th Cir. 2003).

- The Second Circuit, however, distinguished *Cardizem* since it prohibited the generic maker from marketing non-infringing generic versions of Cardizem and so went beyond the preclusive scope of the patent*. See In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d 187 (2nd Cir. 2006).

The Circuit Split As to Applicability of Antitrust Laws to Hatch-Waxman Settlements

The Federal and Eleventh Circuits:

- In addition to the Second Circuit, two other circuits decided that reverse payment settlements fall under the scope of the patent test and do not violate the antitrust laws unless the patent was obtained by fraud, the infringement suit was a sham, or the agreement expanded the rights granted by the patent. *See*, *e.g*., *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11 Cir. 2012), *cert. granted sub nomine, FTC v. Actavis*, 133 S.Ct. 787 (2012).

The Third Circuit:

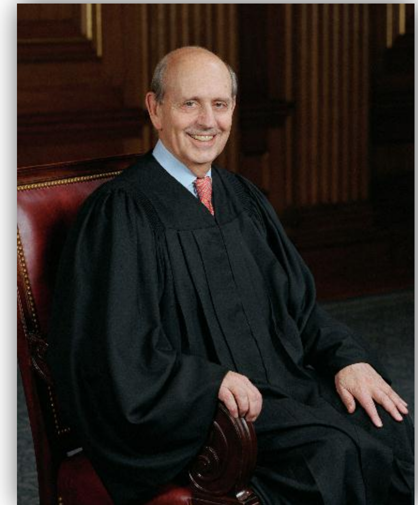
- However, the Third Circuit held reverse payment settlements are presumptively unlawful and should be subject to only a "quick look" or truncated rule of reason analysis. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

The Supreme Court's *Actavis* Decision

- On June 17th, the Supreme Court held, in a majority opinion by Justice Breyer, that:
  - Reverse payment settlements can "**sometimes** violate the antitrust laws." (emphasis added)

- The decision of the Eleventh Circuit dismissing the FTC's complaint was reversed and the case remanded for analysis under the rule of reason.

- The Court struck a middle ground by rejecting arguments that such settlements are presumptively unlawful or generally protected by the "scope of the patent" test.



The Majority's Rationale

- A reverse payment, where large and unjustified, creates the risk of significant anticompetitive effects.
- The brand manufacturer may well possess market power derived from the patent.
- The brand manufacturer making such a payment may be unable to explain and justify it.
- A court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent.

The Dissent

- The majority's logic "cannot possibly be limited to reverse payment agreements or those that are 'large'. The Government's brief acknowledges as much, suggesting that if antitrust scrutiny is invited for such cash payments, it may also be required for 'other consideration' and 'alternative arrangements'."

- The majority's rule discourages settlements as "no incentive exists to settle if, immediately after settling, the parties would have to litigate the same issue—the question of patent validity—as part of [an antitrust] defense."

Failures of the *Actavis* Decision

Breyer's majority opinion is flawed in two substantial ways:

- No clear-cut standards are given to identify which Hatch-Waxman settlements violate antitrust laws.
- The size of the brand's cash payments is given too much weight and insufficient weight is given to the inherent preclusive competitive effect of patents.

No Clear-cut Standards

- The majority opinion left structuring an appropriate rule of reason analysis of Hatch-Waxman settlements for the lower courts to work out.
- Still, a large, unjustified reverse payment can, in the majority's view, provide a workable surrogate for a patent's weakness, so the FTC is not required to "litigate the patent's validity, …"
- The dissent nonetheless noted that the risk remains that the question of patent validity may have to be litigated in some cases as part of an antitrust defense.

Open Issue – What Cash Payments Are Justified?

Justifications for "reverse" cash payments should include, among others:

- the cash payment amounts to an approximation of the litigation expenses saved through settlement;
- the cash payment reflects fair consideration for other services that the generic maker is contractually obligated to provide, such as manufacturing, distribution, marketing, or promotional services; or
- the generic faced bankruptcy without the cash payment.

Open Issue – Are Hatch-Waxman Settlements That Do Not Include Cash Payments Subject to Rule of Reason Analysis?

- Only cash payments are discussed in the majority opinion.
- This leaves unresolved the issue of whether Hatch-Waxman settlements that provide non-cash compensation or other alternative arrangements are subject to rule of reason antitrust scrutiny.
- The FTC has said a “reverse” payment can be monetary or non-monetary.

Open Issue – the Role of AGs

Sale of AGs during or before a generic's marketing exclusivity period have a pro-competitive effect. The antitrust laws protect competition, not competitors.

- No AG commitments, however, may well prove to be problematic, from an antitrust perspective, as the lower courts develop a rule of reason structure for analyzing Hatch-Waxman settlements.
- More nuanced provisions allowing AGs with a declining royalty structure or solely for certain strengths or modes of delivery, coupled with supply or co-marketing agreements, may prove to be more defensible under a rule of reason analysis.

Open Issue – the Role of AGs

- In the *In re Lamictal Direct Purchaser Antitrust Litig.* case pending in the District of New Jersey, the FTC argued that a brand's commitment not to market an authorized generic ("AG") should be treated like a cash payment because it "can induce a generic company to accept a delayed entry date."

- At issue was a settlement between Teva and GlaxoSmithKline that involved GlaxoSmithKline's agreement not to release its authorized generic version of the name brand epilepsy drug Lamictal.

- The district court held that the Sherman Act only applied to cash payments and dismissed the suit, which was then appealed to the Third Circuit.

- On July 2, 2013, following the *Actavis* decision, the Third Circuit remanded the case to allow the district court to reconsider its dismissal.

Practical Considerations: Early Dismissal Less Likely

- Except for simple agreements setting an early generic entry date, after *Actavis*, it will be nearly impossible to settle Hatch-Waxman patent infringement suits without any antitrust risk.

- Consequently, the dismissal of antitrust suits concerning Hatch-Waxman settlements on motions to dismiss or even summary judgment motions will be much more difficult.

Practical Considerations: Motive

- The motive or intent for an alleged restraint of trade plays an important role in an antitrust rule of reason analysis.

- Thus the preservation of attorney-client and work product privilege and the avoidance of ill-conceived emails and memos is crucially important in connection with the evaluation, prosecution, or defense of a patent infringement suit and ensuing settlement negotiations.

Practical Considerations: Four Year Look Back Period for Challenging Hatch-Waxman Settlements

- The Sherman Act and many state antitrust acts have four-year statute of limitations.
- Hatch-Waxman settlements where generic entry occurred more than four years prior to the filing of an antitrust complaint generally should still be dismissed under the statute of limitations at the outset of the suit.
- Hatch-Waxman settlements where the entry date of the generic occurred less than four years before the filing of the complaint may fall under the continuing violation doctrine. The damage exposure should, however, be limited to alleged overcharges or lost profits attributable to sales within the four year look back period.
- The doctrine of fraudulent concealment has, on occasion, been applied to extend the antitrust four-year statute of limitations.

Practical Considerations: Future Hatch-Waxman Settlements

Hatch-Waxman settlements will have to be structured more defensively, with minimal cash payments and a view to possible rule of reason analysis. No fool proof antitrust shield exists, but the trend towards the following arrangements between brands and generic makers, with commercially reasonable terms, should continue:

- manufacturing, supply, co-marketing and co-development provisions; and
- AG provisions.

Practical Considerations: More FTC Challenges to Hatch-Waxman Settlements

- More FTC reverse payment suits can be anticipated.
- After the *Actavis* decision was handed down, the FTC announced:
  - "We look forward to moving ahead with the Actavis litigation and showing that the settlements violate antitrust law. We also are studying the Court's decision and assessing how best to protect consumers' interests in other pay for delay cases."
- The FTC may well make no AG commitments a target in future antitrust suits.

Practical Considerations: Precedential Value of an FTC Decision

If the FTC wins a reverse payment case, that decision could, in certain circumstances, under the doctrine of collateral estoppel, bar brands from asserting that the reverse payment agreement at issue in the FTC suit is pro-competitive in subsequent antitrust suits by private litigants. *See, e.g., Parklane Hosiery Co., Inc. v. Shore, 439 U.S. 322 (1979).*

Practical Considerations: Antitrust Standing

- Unlike the FTC, private antitrust litigants must allege antitrust standing (that is, direct injury of a sort which the antitrust laws are designed to protect) to survive a motion to dismiss.

- The complex Hatch-Waxman regulatory framework may make demonstrating antitrust standing more difficult for generic competitors who have not obtained at least tentative FDA approval.

Practical Considerations: More State and Private Litigation

- More federal antitrust suits challenging reverse payment settlements may well be brought by private litigants including:
  - direct purchasers; and
  - competitors.
- More suits by state attorney generals challenging such settlements may also be brought under state antitrust laws, consumer protection laws and common law claims for unjust enrichment and unfair competition.

Practical Considerations: Catalyst's "Top 20 Generics Delayed by Pay-For-Delay Deals"

Prescription Drug (and Drug Maker)	Condition the Drug is Commonly Prescribed to Treat	Annual Sales Before Generic ($ millions)[A]	Year of Pay-for-Delay Deal	Length of Delay[B]	Price of Brand-name Drug[C]	vs Price of Generic Drug ($)
Adderall XR (Shire)	Attention deficit hyperactivity disorder (ADHD)	1,500 M	2006	3.0 years[6]	238	102
DELAYED UNTIL 2015 **Aggrenox** (Boehringer Ingelheim)	Stroke risk, blood clots	331 M[7]	2008	6.8 years[8]	294	73†
Altace (Sanofi)	High blood pressure, heart failure	700 M[9]	2006	3.0 years[10]	115	12
DELAYED UNTIL 2015 **AndroGel** (Solvay Pharmaceuticals/ Abbott Laboratories)	Low testosterone in patients with AIDS, cancer and other conditions	1,332 M[11]	2006	8.7 years[12]	379	96†
BuSpar (Bristol-Myers Squibb)	Anxiety	600 M[13]	1994	6.25 years[14]	not available[15]	12
Caduet (Pfizer)	High cholesterol and coronary artery disease	266 M	2008	1.7 years[16]	266	113
Cipro (Bayer)	Bacterial infection, anthrax exposure	1,300 M[17]	1997	7.0 years[18]	346	23
Effexor XR (Wyeth/Pfizer)	Major depressive disorder, anxiety and panic disorder	2,400 M	2005	4.7 years[19]	194	17
K-Dur (Schering-Plough/Merck)	Low blood levels of potassium (hypokalemia)	250 M[20]	1997	4.0 years[21]	not available[22]	21
Lamictal (GlaxoSmithKline)	Epilepsy, bipolar disorder, Lennox-Gastaut Syndrome	1,500 M	2005	3.0 years[23]	465	14

Excerpted from "Top Twenty Pay-for-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers," U.S. PIRG and Community Catalyst (July 2013), *available at* http://www.communitycatalyst.org/newsroom/press_releases?id=0189

Pending Federal Legislation

- In view of the *Actavis* decision, pending legislation regarding reverse payment settlements is unlikely to pass.

- While the initiative in Europe for joint action against reverse payment settlements may create renewed interest in Washington for congressional action, it remains unlikely that any legislation will pass this year.