Reverse-payment settlements: The U.S. perspective

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New rules: *FTC v. Actavis*

- On June 17, 2013 the U.S. Supreme Court decided *Federal Trade Commission v. Actavis, Inc. et al.,* 133 S.Ct. 2223 (2013)
- The court held that reverse-payment settlements **can violate the antitrust laws**.
- After *Actavis*, reverse-payment settlements are analyzed under the **rule of reason**. The *Actavis* rule of reason:
  - Incorporates certain plaintiff-friendly inferences
  - Limits potential business justifications
  - Expands the reach of the antitrust laws in policing IP-related conduct

Background: Hatch-Waxman Act

Pharmaceutical competition in the US is subject to an elaborate regulatory scheme:

1. Following a New Drug Application ("**NDA**") by the innovator, the FDA approves the drug for marketing. This is a very expensive and time consuming process.

2. The generic firm files an abbreviated NDA ("**ANDA**") to market a competing drug without having to repeat the NDA process. If the ANDA filer claims that the innovator's patents are invalid or not infringed, then the ANDA filing counts as patent infringement. ("Paragraph IV certification")

3. The innovator sues the generic for patent infringement. The FDA must not approve the generic for 30 months while the parties litigate.

4. If the (first ANDA-filer) generic firm wins, then it gets 180 days of generic exclusivity, effectively creating a duopoly. After that, other generics may enter the market as well.

Settlement incentives

Suppose that innovator A has 10 years of patent exclusivity remaining. Generic B challenges A's patents with an ANDA filing. A sues B for patent infringement.

1. A wants to keep B out of the market for as long as possible. Exclusivity is often worth hundreds of millions.

2. B wants to secure the 180 day bounty. Much of the profits from generic entry are realized during the duopoly window.

Private agreements affecting consumers

Resolving B's challenge through patent litigation exposes both A and B to risk. A may lose exclusivity, B may lose the bounty. This creates an opportunity for **privately efficient** agreements. For example:

1. B drops its challenge and gives A more time to exploit its patent monopoly (A gets time)

2. A guarantees B the 180 day exclusivity (B gets certainty)

3. If A stands to gain more from this agreement than B, A may pay B a share of the monopoly gains.

The problem is that the privately efficient agreement may adversely affect (static) consumer welfare through higher prices from delayed generic entry.

Judicial treatment

Starting point: Company A paying competitor B to stay out of the market is illegal under §1 of the Sherman Act. *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990).

Complications: The pharmaceutical regulatory scheme complicates matters. It has been argued that:

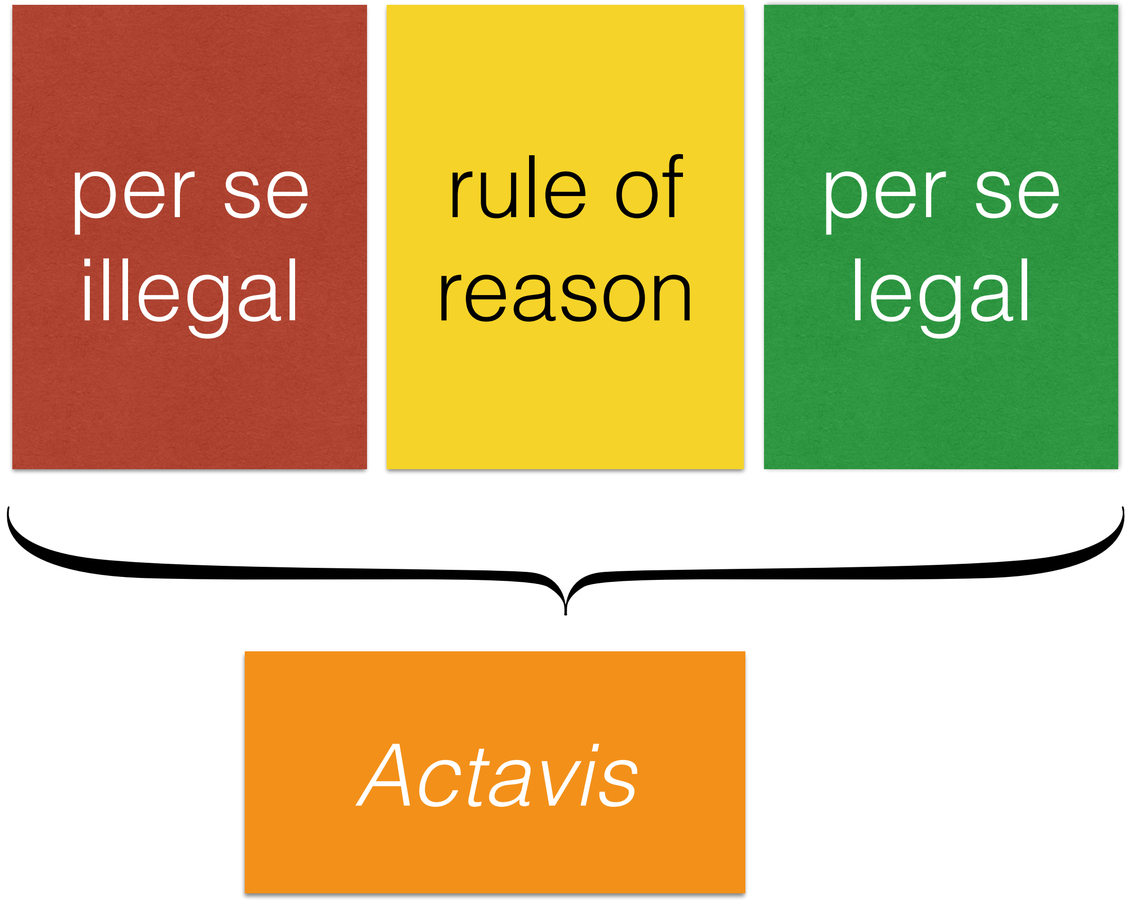
1. B is not really a competitor, because A has a patent right to lawfully exclude B. Patents are presumed valid until invalidated.

2. The Hatch-Waxman Act pushes parties towards litigation. Patent litigation is expensive. Settling patent litigation is efficient.

3. The 180 day duopoly bounty creates incentives for parties to settle. Some have argued that settlements are thus an intended part of the regulatory scheme.

Inconsistent resolutions

- Some courts have held that payments for delay are ***per se* illegal**. *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).
- Other courts have been highly deferential, making reverse-payment settlements almost ***per se* legal**. *In re Tamoxifen Citrate Antirust Litigation*, 466 F.3d 187 (2d Cir. 2006); *In re Ciprofloaxin Hydrocloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008).
- Other courts yet have relied on variants of the **rule of reason**.
  - Some more plaintiff-friendly ("quick look"), *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3rd. Cir. 2012).
  - Others more defendant-friendly, *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11th Cir. 2012).
- *Actavis* resolves the circuit split, applying the rule of reason, but rejecting a "quick look" approach.



Actavis: Basic facts

1. Solvay obtained a patent on AndroGel
2. Actavis filed an ANDA with Para. IV certification
3. Solvay sued Actavis for patent infringement
4. After the 30-month stay expired, the parties settled
    - Actavis agreed to **delay entry** for 9 years
    - Solvay agreed to **pay** at least $171 million to Actavis ($19 - $31 million/year for 9 years)
    - Actavis agreed to help Solvay **promote** AndroGel

Procedural history

The FTC sued the parties under §5 of the FTC Act for unlawfully agreeing "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years."

- Trial court: **The FTC lost**. The court dismissed the FTC's antitrust complaint.

- Court of appeals: **The FTC lost**. The court affirmed the dismissal. "[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *FTC v. Watson Pharmaceuticals, Inc*. 677 F.3d 1298, 1312 (11th Cir. 2012)

- Supreme Court: **The FTC won**. The court reversed 5-3 and held that: [R]everse payment settlements … can sometimes violate the antitrust laws." *FTC v. Actavis*, at 2227.

Legal standard: Rule of reason

"The FTC must prove its case as in other **rule of reason** cases." *FTC v. Actavis*, at 2237.

- No *per se* illegality
- No *per se* legality
- No "quick look" rule of reason

Elements of a rule of reason claim: (1) market power; (2) anticompetitive effects; (3) procompetitive efficiencies.

"Actual preclusive scope"

- The court rejected the "scope of the patent" test, i.e., antitrust immunity for conduct whose anticompetitive effects are within (a) the temporal and (b) subject matter scope of a patent.

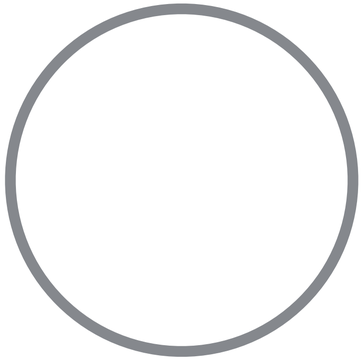
- "The patent here may or not be valid and may or may not be infringed." Id. at 2231. What matters is not the abstract "**exclusionary potential"** of the patent but "its **actual preclusive scope**." Id.

- Here, the settlement may have expanded the actual preclusive effect of the patent, replacing the *possibility of immediate exclusion* with *nine years of certain exclusion*.

- The settlement thus "prevent[ed] the risk of competition. And … **that consequence constitutes the relevant anticompetitive harm**." Id. at 2236.

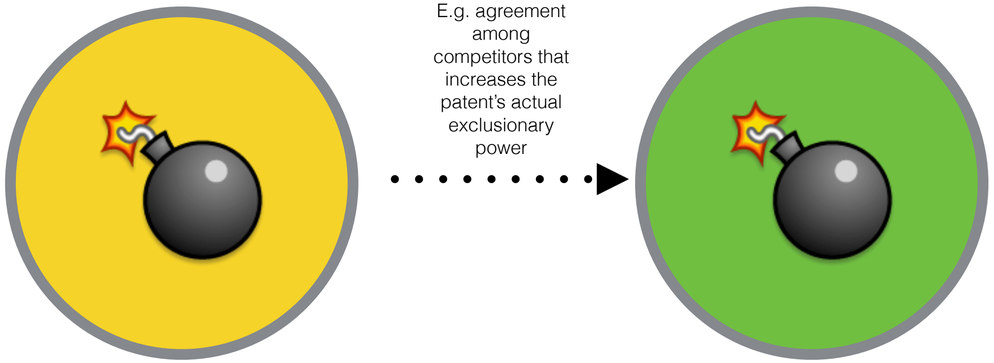
Potential v. actual preclusive scope

Potential scope of the patent
(time, subject matter)



Adverse effects
Inside = OK
Outside = AT

Actual scope of the patent
(time, subject matter, strength)



Adverse effects
Inside = AT
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Unobjectionable settlements

The court introduced the following classification of settlements and reverse payments:

1. **Unobjectionable settlements**: Settlements delaying entry "without the patentee paying the challenger" are unobjectionable. Id. at 2237.

2. **Unobjectionable payments**: Settlement payments from the patentee to the infringer for (a) avoided **litigation costs** and (b) **services provided** and properly valued are unobjectionable. Id.an at 2236. (Note: The court also included an undefined "other" category.)

Focus on “unexplained payments”

Any additional unexplained reverse payment is prima facie suspect.

- It “[i]s a strong indicator of ... the **power to charge prices** higher than the competitive level.” Id. at 2236. (“Market power”)
- It suggests that “a patentee is using its monopoly profits to **avoid the risk of patent invalidation**.” Id. at 2236. (“Anticompetitive effects”)
- It “would normally suggest that the patentee has **serious doubts** about the patent's survival.” Id. at 2236. (“Lack of efficiencies”)

Limits on traditional defenses

Concern: “Public policy **favors settlements** over litigation.”

- “We recognize the value of settlements and the litigation problem. But we nonetheless conclude that this patent-related factor should not determine the result here.” Id. at 2234.

Concern: “Conducting a patent trial within an antitrust trial to ascertain the actual patent strength is **unadministrable**.”

- “[I]t is normally not necessary to litigate patent validity to answer the antitrust question ... The size of the unexplained payment can provide a workable surrogate for a patent's weakness.” Id. at 2236-37.

Open issues: Non-cash payments

- *Actavis* did not expressly address non-cash compensation for delayed generic entry.

- In *In re Nexium Antitrust Litigation*, 2013 WL 4832176 (D. Mass. Sept. 11, 2013) the innovator allegedly promised not to launch an authorized generic in exchange for delayed entry.

- "Nowhere in *Actavis* did the Supreme Court require some sort of monetary transaction to take place for an agreement between a brand and a generic manufacturer to constitute a reverse payment." Id. at 15.

Summary

1. The **rule of reason** applies to reverse payment settlements.

2. There is **no automatic antitrust immunity** for reverse patent settlements within the potential "scope of the patent."

3. **Unexplained large reverse payments** create inferences favoring the plaintiff, thus modifying the ordinarily defendant-friendly rule of reason.

4. Going forward, both innovators and generic firms should carefully **analyze their settlement strategies** within the *Actavis* framework.