Competition Law Treatment of Patent Settlements in the US

Michael Egge

25 November 2013
FTC v. Actavis in a nutshell

- Reverse payment settlements are neither automatically immune from antitrust liability nor presumptively illegal, but rather assessed under a rule of reason.
- Large, “unexplained” reverse payments create inferences favoring the plaintiff, thus apparently modifying the ordinarily defendant-friendly rule of reason.
- Settlements delaying entry “without the patentee paying the challenger” and settlement payments for avoided litigation costs and/or services provided are unobjectionable.
- Significant departure from deference given conduct within the scope of the patent.
- Expands reach of antitrust laws to policing IP-related conduct.
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. Very expensive, time consuming process.

2. 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, 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.
The Reverse Settlement Phenomenon

- Hatch-Waxman accelerates the normal path to an infringement action and substantially alters a generic’s cost/benefit calculus in triggering patent litigation
  - No entry required/no damage exposure
  - The duopoly window carrot

- Innovators, however, now face more litigation earlier, and yet no prospect of damages for prevailing

- Regulatory landscape creates incremental settlement incentives: innovator wants to preserve exclusivity and generic wants the duopoly window

- As a result, some originator companies have paid substantial sums to generic companies to settle infringement actions triggered by Para IV certification
Starting point: Company A paying competitor B to stay out of the market is illegal under § 1 of the Sherman Act

Not so simple: The patent and pharmaceutical regulatory considerations complicate matters. It has been argued that:

1. B is not really a competitor because A has patent right to lawfully exclude B. Patents presumed valid until invalidated. Thus settlements with restrictions within scope of patent are consistent with A’s right to exclude.


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

Split developed in the Courts of Appeal

- Sixth Circuit → settlements are per se illegal
- Second, Eleventh and Federal Circuits → settlements are per se lawful if within the scope of the patent
- Third Circuit → settlements are presumptively unlawful/inherently suspect (truncated rule of reason)


3. Solvay sued Actavis for patent infringement

4. After 30-month stay expired, the parties settled (2006)
   - Actavis agreed to delay entry for 9 years; 65 months before Solvay’s patent expired
   - Solvay agreed to pay at least $171 million to Actavis ($19-31 million/year for 9 years)
   - Actavis agreed to help Solvay promote AndroGel to urologists.

5. FTC sued under Section 5 of FTC Act in 2009, trial court dismissed and court of appeals affirmed: “Absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack as 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)
The Decision

- Supreme Court rejects scope-of-patent test
  - Court focused on the risk that a reverse payment for giving up the patent fight expands 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.” FTC v. Actavis, Inc. et al., 133 S.Ct. 2223, 2236 (2013)

- Adopts rule of reason and rejects “quick look”

- Regards as unobjectionable:
  - Settlements delaying entry without payment
  - Payments for avoided litigation costs and services provided

- Additional “unexplained” payment, however, is prima facie suspect because
  - Strong indicator of power to charge high prices (market power)
  - Patentee using monopoly profits to avoid risk of patent invalidity (bad effects)
  - Suggests patentee has serious doubts about patent (lack of efficiencies)

- Suggests no need to litigate patent validity: “[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.
• Arguably a “down the middle” outcome
• Chaos or order?
  • Not clear trial courts can avoid validity inquiry
  • Dissent: “Almost all of [the majority’s concerns] are unresponsive to the basic problem that settling a patent claim cannot possibly impose unlawful competitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful. ... I therefore don’t see how the majority can conclude that it won’t normally be necessary to litigate patent validity to answer the antitrust question, ... unless it means to suggest that the defendant (patent holder) cannot raise his patent as a defense in an antitrust suit. But depriving him of such a defense–if that is what the majority meant to do–defeats the point of the patent, which is to confer a lawful monopoly on its holder.”
• Consistent with trend to rule of reason and confidence in ability of courts to apply it
• Potential shift in the intersection of antitrust and IP law in the US