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Reverse Settlements in US Antitrust Law

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Overview

- Background: Hatch-Waxman
- FTC (and DOJ) Position
- Reverse Settlement Cases (2005-2012)
- *FTC v. Avartis* – Supreme Court (June 2013)
- A comparative law perspective

Background: Hatch-Waxman

- Amendments (1984) to Federal Food, Drug and Cosmetic Act (sponsored by Senator Hatch and Congressman Waxman):
  - simplify process of bringing generic drugs to market
  - provide incentives to generic producers
- Key features
  - Expedited generic entry through ANDA (rely on safety and effectiveness finding in NDA)
  - Incentive for generic producer to move quickly (180 day exclusivity)
  - Tool for flushing out weak IP (Paragraph IV certification)

Background: Hatch-Waxman

- FDA can grant ANDA effective as soon as patents claimed on NDA expire
- Alternatively, applicant for ANDA can certify that generic product does not infringe patent or that patent is invalid (Paragraph IV certification)
  - NDA holder has 45 days to file infringement suit
  - If suit filed FDA can grant ANDA 30 months after initial application

The Reverse Settlement Phenomenon

- Hatch-Waxman created incentives for patent litigation involving generic competitors
  - Costs for filing ANDA are low
  - Originator must start infringement action
- Some originator companies paid substantial sums to generic companies to settle infringement actions triggered by Para IV certificates
  - Paying off first ANDA holder reduced incentive for subsequent generics
- FTC maintains that such settlements are not found outside Hatch-Waxman context

The FTC Position

- FTC contends that payment to rivals not to compete is a classic antitrust violation
  - Litigants are sharing monopoly profit
  - Benefit of early generic entry (goal of Hatch-Waxman) is lost
  - Initially focused on payments
  - Subsequent focus on broader commercial benefits to generic
- FTC can apply Section 5 FTCA
  - both restrictive agreement and monopolisation theories

The DOJ Position

- DOJ in Bush administration argued that reverse settlement *could* be issue
  - Rule of reason approach
  - Strength and scope of patent was key
- Obama administration DOJ adopted FTC approach

Reverse Settlement Cases (2005-2012)

- Initially FTC did not have great success in pressing its reverse settlement theory
- *Schering Plough Corp. v. FTC* (2005): 11th Circuit Court of Appeals rejected FTC theory
  - Settlement only unlawful if outside of "scope of patent"
    - obtained by fraud
    - suit not objectively baseless (sham litigation)
    - no restrictions beyond scope of patent
  - Based on principle of IP law that properly granted patent is presumed to be valid

Reverse Payment Cases (2005-2012)

- Other courts followed *Schering Plough* "scope of patent" analysis, *e.g.*:
  - *In re Tamoxifen Citrate Antitrust Litigation* (2d Circuit 2005)
  - *In re Ciproflaxin Hydrochloride Antitrust Litigation* (Federal Circuit 2008)
- In 2012, Third Circuit ruled, however, that reverse payments were presumptively anticompetitive
  - *In re K-Dur Antitrust Litigation* (24 Aug. 2012)
- This set stage for *FTC v. Actavis*

FTC v. Actavis

- Hatch-Waxman litigation between Solvay and two generic producers:
  - Paddock Laboratories (with its partner Par Pharmaceutical Co.)
  - Watson Pharmaceuticals (now Activis)
- Litigation involved follow-on patent covering synthesised testosterone product
  - January 2003: Patent issued
  - May 2003: ANDA applications submitted with paragraph IV certification
  - January 2006: FDA granted ANDA
- Watson and Paddock/Par anticipated entry in 2007
- Solvay anticipated
  - 90% sales drop in year after entry
  - loss in profit of $125 million annually

FTC v. Actavis: Settlement Terms

- Entry delayed to 2015
- Annual payments:
  - Watson: $19-30 million “ostensibly” (according to FTC) to market product to urologists
  - Paddock: $2 million to serve as back-up supplier
  - Par: $10 million to market product to primary care doctors

FTC v. Actavis: Lower Courts

- Action for injunctive relief under Section 5 FTCA
  - Brought in California
  - Transferred to Georgia -- part of 11th Circuit
- FTC alleged Solvay had less than 50% chance of success
  - Thus distinguishing *Schering Plough*
- District Court dismissed based on scope of patent rule
- Court of Appeals affirmed
  - Antitrust litigation not suited for resolving patent strength ("Turducken" problem)

FTC v. Actavis: Supreme Court (17 June, 2013)

- Supreme Court granted writ of *certiorari* to resolve dispute between circuits on reverse settlements
- 5-3 Decision reversing Court of Appeal (Majority Opinion by Justice Breyer)
  - "Scope of patent" rule rejected -- Court must resolve IP law / Antitrust law conflict by balancing the privileges granted to the patentee against traditional antitrust interests

    > "Whether a particular restraint lies 'beyond the limits of the patent monopoly' is a *conclusion* that flows from that analysis and not, as THE CHIEF JUSTICE suggests, its starting point."
- Court also rejected test proposed by FTC
  - Reverse settlements not presumptively unlawful
- Court endorsed a rule of reason approach

Antitrust Policy Interests Favouring Intervention (according to SCt)

- Reverse settlement payments have a potential for genuine adverse effects on competition
  - Incumbents usually have substantial market power
  - successful challenge of patent would lead to consumer welfare gain
  - Time periods for approval under Hatch-Waxman mean that further generic producers will not necessarily appear
- There will not always be a justification for these consequences
- No need to litigate validity or infringement
- Parties can use other settlement mechanisms
  - *Example: a*greement on delayed entry

The *Activis* Rule of Reason

- The Court rejected "quick look" presumption of Invalidity because this was not case

  "where observer with even rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."

- Likelihood of anticompetitive effects depends on
  - size of payment
  - relationship of payment amount to future litigation costs
  - relation of payment amount to other services for which it might represent payment
  - "lack of any other convincing justification"

The *Activis* Rule of Reason – Key Role for Size of Payment

- A central issue at the oral argument in *Actavis* was need to assess the merits of the IP case
  - From an economic perspective the existence or extent of competitive harm depends strongly on strength of patent
  - Assessing strength of patent is role of patent court not antitrust issue
- The Court suggests that this problem can be avoided by focusing on the size of the reverse payment:

  > "In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."

FTC v. Actavis: Unresolved Issues

- Lack of specificity in *Actavis* rule of reason test is not surprising
  - neither the parties nor the lower courts had argued for a rule of reason approach
  - Pre-2009 DOJ approach focused on weakness of IP rights
- What does plaintiff need to prove?
  - Is showing “large payment” sufficient to shift burden of justification to defendants?
- When is a payment “large”?
  - Are avoided litigation costs /other services only criteria?
  - Is profit that generic would make if entry were successful relevant? (Avoids sharing of monopoly profit).

FTC v. Actavis: Unresolved Issues

- What is permissible “payment”?
  - In August 2013 filing FTC argued that grant of exclusive “authorised generic” rights was impermissible because outside scope of what generic could get in litigation
- What other economic justifications might be relevant?
  - Could payment be justified if it facilitated agreement on generic entry before patent expiration?
  - Could payment be justified as insurance against risk of under-compensation where generic enters market and subsequently loses infringement action (and then becomes insolvent)?

FTC v. Actavis: Unresolved Issues

- Is strength of patent entirely off the table?
  - Supreme Court indicated that eliminating even a small risk of invalidity could give rise to anticompetitive harm
  - But likelihood of success in patent litigation may affect economic justifications

Implications for EU Debate

- Caution is in order
  - Hatch-Waxman regulatory structure provides essential context for the US antitrust assessment
  - Patent Act, Hatch-Waxman, Antitrust laws: all Federal statutes
    - No institutional reason for SCt to favour competition policy
    - If presumption of validity is part of patent law – SCt can change that
  - The debate between “rule of reason” and “quick look” has its own history
    - Not directly comparable to object/effect distinction in Art. 101(1) TFEU