LATHAM & WATKINS LLP

Reverse Settlements State of Play in US Antitrust Law

John Kallaugher

17 May, 2013

Overview

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

Background: Hatch-Waxman

- Hatch Waxman amendments (1984) to Federal Food, Drug and Cosmetic Act:
  - 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
    - can't just threaten injunction 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
- DOJ now follows FTC line

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 sets 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
- SCt granted writ of *certiorari* to resolve dispute between circuits on reverse settlements

FTC v. Actavis: Supreme Court

- Solicitor General (for FTC) argued for rule of presumptive illegality ("quick look" test)
  - Reverse payment (or benefit) unlawful unless justified
- Possible justifications
  - Benefit was for something other than delay –*bona fide* fair consideration for property or services
  - Payment commensurate with litigation costs avoided by originator
  - other business justification (in exceptional circumstances)
- Respondents argued for scope of patent rule

FTC v. Actavis: Supreme Court

- Oral Argument (25 March, 2013) – issues addressed
  - Is there precedent for antitrust infringement within scope of patent?
  - Full rule of reason or "quick look"?
  - Can antitrust analysis dispense with assessing strength of patent?
  - Should antitrust law be stretched to correct deficiencies in Hatch-Waxman?
    - *Twombley* argument?
    - Applies to both scope of patent vs. rule of reason and rule of reason vs. "quick look"

FTC v. Actavis: Supreme Court

- Oral Argument (25 March, 2013) – issues addressed
  - If there is a presumption, should Court define criteria for showing benefits (or leave to lower courts to develop)?
  - Should there be *cap* on payment based on profit that generic would make if entry were successful?
  - Why won't possibility of further generics seeking pay-off eventually make reverse payment strategy unprofitable?

FTC v. Actavis: Supreme Court

- Risky to predict SCt result from oral argument
  - But of seven Justices who asked questions, only Justice Scalia appeared attracted to pure scope of patent argument
  - Some Justices appear unconvinced by need for "quick look" analysis
  - Support for position that strength of the patent should play role in analysis

Implications for EU Debate

- Caution is in order
  - Hatch-Waxman regulatory structure provides essential context for the US antitrust assessment
    - Evident from oral argument in SCt
  - 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 in SCt between "rule of reason" and "quick look" has its own history
    - Not directly comparable to object/effect distinction in Art. 101(1) TFEU