FTC v. Actavis: Reverse Payments to Settle Hatch-Waxman Litigation

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ROPES & GRAY

FTC opposes Pay-For-Delay

- *To Promote Competition: The Proper Balance of Competition and Patent Law and Policy* (FTC 2003)
  - http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf
- *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions*
  - FTC Staff Study, January 2010
- FTC Annual Report 2012
  - http://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement

Before 2011, Courts applied “Scope of patent” test

- Eleventh Circuit
  - *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003)
  - *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005)

- Second Circuit
  - *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006)

- Federal Circuit
  - *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008)

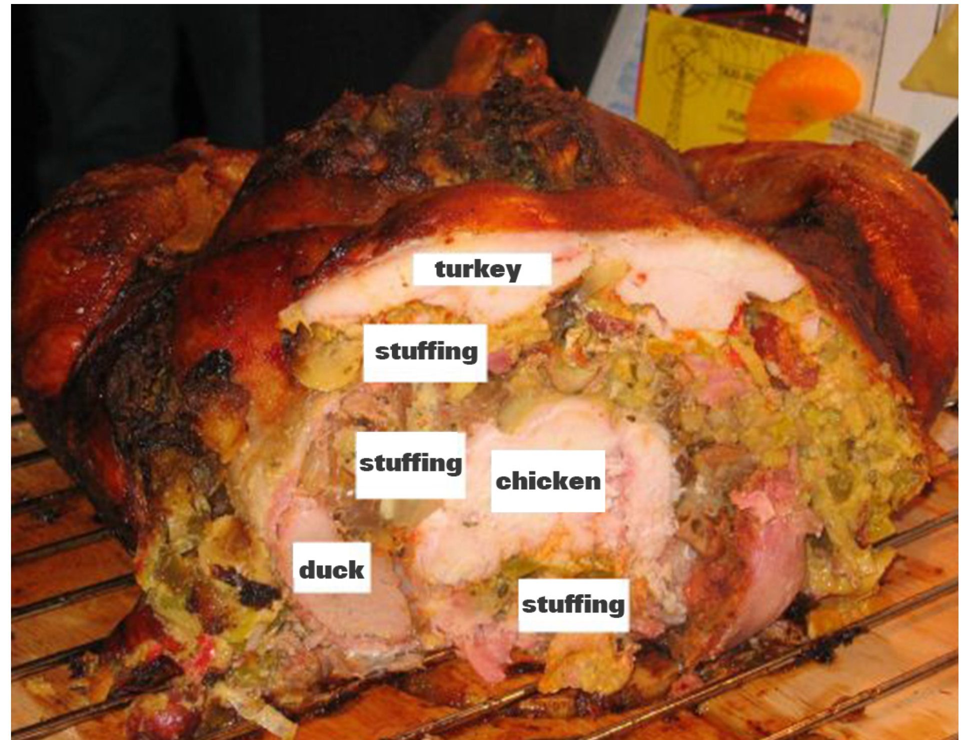
2011-2012: Circuit conflict

- *In re K-Dur Antitrust Litigation,* 686 F.3d 197 (3d Cir. 2011)
  - "Scope of patent test" is contrary to antitrust policy
  - Supreme Court law (*Lear,* 1969) encourages challenging "weak" patents
  - Hatch-Waxman Act policy is to facilitate generic entry
  - Pay-for-delay is presumptively bad under "quick look" analysis

- *FTC v. Watson,* 677 F.3d 1298 (11th Cir. 2012)
  - Reaffirms "scope of patent" test
  - Reaffirms that public policy favors settlement of litigation
  - No reasonable way to assess "strength" of patents in litigation

Assessing the strength of the asserted patents

- “[W]e would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task.”
  - *FTC v. Watson*, 677 F.3d. 1298, 1315 (11th Cir. 2012)



The Supreme Court Splits the Baby

- *FTC v. Actavis,* 133 S.Ct. 2223 (June 17, 2013)
  - Scope of patent test makes sense only for patents that are valid and infringed
  - Hatch-Waxman Act suggests that antitrust is a concern
  - Not all settlements are immune from antitrust review
- Court rejects *per se* or “quick look” in favor of “rule of reason: analysis
  - Reverse payment may be reasonable
  - But an unreasonably large payment may indicate unreasonable restraint of trade and market power, etc.

How broad a decision?

- **“The likelihood of a reverse payment bringing about anticompetitive effects** depends upon its size, its scale in relation to the payor’s anticipated litigation costs … and the lack of any other convincing justification. The existence and degree of any anticompetitive effects **may also vary as among industries**.”
  - *FTC v. Actavis* 133 S.Ct. 2223, 2237 (2013)

- Is *Actavis* limited
  – Just to pharma?
  – Just to pay-for-delay, regardless of industry?
- Or will antitrust principles now apply more broadly to all patent licensing?

The patent misuse doctrine

- Old: “the nine no-nos”:
  - Tying
  - Mandatory grant back
  - Restricting resale
  - Restricting dealing outside patent scope
  - Horizontal agreement for no further licenses
  - Mandatory package license
  - Royalties not reasonably related to patented sales
  - Restrictions on use
  - Minimum resale price
- Current
  - 1988 Amendments to 35 U.S.C. § 271(d)
  - *Princo Corp. v. Int’l Trade Comm’n,* 616 F.3d 1318 (Fed. Cir. 2010): Federal Circuit (en banc) applies misuse doctrine narrowly, using “scope of the patent” test

What else might be "misuse"?

- Conduct involving standards and standards bodies?
  - Standards essential patents
  - FRAND issues
- Conduct by patent assertion entities?

- See, generally, Lim, *Patent Misuse and Antitrust: Rebirth or False Dawn*, to be published 2014 in 20 Mich. Telecom & Tech. L. Rev.