Reverse Payments & the DOJ

Bates White Healthcare Law & Economics Workshop:

Healthcare Reform—Implications For Competition Policy & Analysis

October 29, 2009

Jim O'Connell

Disclaimer & Contact Information

- For further information, or if you have any questions, the author may be contacted at:

Jim O'Connell
Covington & Burling LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004
(202) 662-5991
joconnell@cov.com

- Please note that this slide deck is incomplete without the accompanying oral presentation and in no event constitutes legal advice that may be relied upon with respect to any party or circumstance.

Department of Justice

- Antitrust Division
- Solicitor General
- DOJ & the Federal Trade Commission
  - Share civil enforcement of antitrust laws
  - Pharmaceutical industry traditionally within FTC's area of expertise
  - FTC part of executive branch but has authority to represent itself before the Supreme Court

DOJ Briefs in Reverse Payment Cases

- July 2004: *Andrx Pharmaceuticals v. Kroger*
  - CVSG brief in "Cardizem" case from 6th Circuit
- May 2006: *Schering-Plough Corp. v. FTC*
  - CVSG brief in "Schering" case from 11th Circuit
- May 2007: *Betty Joblove v. Barr Laboratories*
  - CVSG brief in "Tamoxifen" case from 2nd Circuit
- July 2009: *Ciprofloxacin HCL Antitrust Litigation*
  - ATR Division "Cipro" brief in response to 2nd Circuit's invitation

Andrx Pharmaceuticals v. Kroger (2004)

- Attempt to bring remnants of 6th Circuit *Cardizem* case before SCOTUS
  - Interim settlement
  - Settlement also covered non-infringing products
  - Per se unlawful
- DOJ & FTC (CVSG brief) recommended "no cert"
  - Rule of Reason, not Per se
    - Public interest in settlements
    - Patent holder has right to exclude
    - But settlements can result in less competition
  - But case not appropriate vehicle
    - Settlement construed as covering other products so likely exceeded scope of exclusion provided by patent at issue (per se treatment may have been warranted)
    - Relatively rare case of an interim settlement
    - Recent amendments to Hatch-Waxman

Schering-Plough v. FTC (2006)

- ALJ: agrmt did not unreasonably restrain competition
  - Payment to Upsher part of bona fide licensing agreement
  - No substantial, reliable evidence that ESI payment was to secure unlawful delay
  - Evidence that generics would have entered earlier absent payments?
- FTC reversed ALJ
  - Payments delayed entry: likely anticompetitive
  - Absent offsetting consideration, logical to conclude $$ = quid pro quo
  - “License” payments too high to be “reasonably necessary element of a settlement that is procompetitive overall”
  - No need to evaluate likelihood that Schering would prevail on patent infringement claim

Schering-Plough v. FTC (2006)

- 11th Circuit reversed FTC
  - Patent gave right to exclude, and settlements were within scope of patent's exclusionary power
  - Antitrust analysis must take into account
    - Scope of patent's exclusionary potential at the time of the settlement (must evaluate strength of patent)
    - Extent to which settlement exceeds that potential
    - Any resulting anticompetitive effects
  - Reverse payments natural by-product of H-W
  - Substantial evidence that payments were part of legitimate license agreement

Schering-Plough v. FTC (2006)

- FTC petitioned SCOTUS for cert (August 2005)
  - "[F]ormalistic approach to the issue of the 'exclusionary potential' of the patent ignores . . . the existence of *uncertainty* regarding whether a patent is valid."
  - "Probabilistic Patent" theory (Lemley & Shapiro)
    - Patent is qualified property right – really just "right to sue"
    - Consumers have "expected" gain from challenges = actual gains if patent invalidated, discounted by probability of patent being upheld
    - Settlement cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation. Consumers also have "property right"—to level of competition that would have prevailed, on average, with litigation
    - FTC: Patent not a right to exclude, but right to try to exclude
  - 11th Circuit misapplied substantial evidence standard

Schering-Plough v. FTC (2006)

- SG (CVSG brief) recommended "no cert" (May 2006)
  - Echoed policy concerns of SG's *Andrx* brief
    - H-W: reverse payments likely even when patentee's claims strong
    - Don't want standard that props up weak patents, but also don't want standard that results in automatic or near-automatic invalidation of legitimate settlements
  - Seemed wary of "probabilistic patent" theory
    - Must be some evaluation of strength of patent, viewed *ex ante* -- objective evaluation (e.g., a lot of $$$ doesn't = weak patent)
- Not good vehicle
  - Legitimate license payment or pay-for-delay?
  - "Substantial evidence" test: Did court sufficiently defer to FTC?
  - 11th Circuit did not squarely address "probabilistic patent" theory, (only advanced by FTC in its cert petition). No other court of appeals has expressly considered FTC's "expected value" analysis.
  - No genuine circuit split

Betty Joblove v. Barr Laboratories (2007)

- 2nd Circuit Tamoxifen case
  - Rule of reason
  - No assessment of strength of patent claim
  - 3-part analysis:
    - Did settlement exceed scope of patent?
    - Did settlement involve fraud?
    - Was underlying lawsuit objectively baseless?
- SG (CVSG brief) recommended "no cert" (May 2007)
  - 2nd Circuit standard incorrect: goes to far
  - Echoed policy concerns of *Andrx* and *Schering* briefs
  - Court should take into account relative likelihood of success of parties' claims, viewed *ex ante*
  - Case not good vehicle
    - Sherman Act claims moot: patent had expired
    - Relation of state law claims to question presented not clear

In re Ciprofloxacin HCL (2009)

- EDNY—March 2005 (pre-dates 2nd Circuit's *Tamoxifen* decision)
  - Rule of reason
  - No *post hoc* examination of patent's validity
  - Were any adverse effects of settlement "outside the exclusionary zone of the patent"?
  - Absent fraud or objectively baseless patent case, no injury to market cognizable under antitrust law as long as competition is restrained only within scope of patent
  - Rejected plaintiffs' probabilistic patent argument
    - Doesn't translate well into realities of litigation
    - No support in the law for idea that there is a public property right in the outcome of private lawsuits
    - No legal basis for restricting rights of patentees to choose their enforcement vehicle
    - View that "every patent is a little bit invalid" inconsistent with presumption of validity afforded by Congress

In re Ciprofloxacin HCL (2009)

- Most of *Cipro* case now before the 2nd Circuit, which sought views of the U.S. in April 2009
- Followed change of administration in Jan. '09
  - New FTC Chairman: Jon Leibowitz
    - "Eliminating these deals is one of the FTC's highest priorities."
  - New SG: Elena Kagan
  - New AAG: Christine Varney
    - Pledged to "work with the DOJ to align the FTC and the DOJ on the reverse payments issue. And if the courts continue to not reach the result that [the Senate Judiciary Committee] thinks is appropriate, then legislation may be necessary."
  - New Deputy AAG for Economics: Carl Shapiro
    - Co-father of probabilistic patent theory

In re Ciprofloxacin HCL (2009)

- DOJ (ATR) invited by 2nd Circuit to submit *amicus* brief
  - Second bite at *Tamoxifen* apple (some tension w/*Joblove*)
  - Effort to move closer to FTC views, at least rhetorically
  - Effort to rehabilitate probabilistic patent theory rejected by district court
- Balance struck by Congress in Patent Act between
  - enforcing valid patent rights (encourages innovation), and
  - providing for invalidation of "undeserved patents" (protects competition and consumers)
- 2nd Circuit's *Tamoxifen* standard wrong—same view expressed in *Joblove* brief, but with new explanation:
  - Permits patent holders to contract their way out of the statutorily-imposed risk of invalidation
  - No protection to the public interest in eliminating undeserved patents.
  - "There is significant risk of invalidation through litigation."

In re Ciprofloxacin HCL (2009)

- Rejects per se in favor of rule of reason, but moves DOJ closer to FTC
  - *e.g.*, strong suspicion of payments, especially if large
- Reverse payments presumptively unlawful on *prima facie* showing:
  - Generic withdrew its challenge to patent's validity
  - Money or other consideration passed from patentee to generic challenger
  - Payment accompanied agreement to withdraw validity challenge

In re Ciprofloxacin HCL (2009)

- Rebuttable presumption
  - Did terms of settlement impose unreasonable restraint on competition in view of parties' contemporaneous evaluations of likelihood of invalidity judgment?
    - If reasonable explanation for payment, no reason to find that settlement does not provide degree of competition reasonably consistent with parties' contemporaneous evaluations of prospects of litigation success.
    - "Neither necessary nor appropriate to determine whether patent holder would likely have prevailed in patent infringement litigation . . . . Liability properly turns on whether, in avoiding prospect of invalidation . . . parties have by contract obtained more exclusion that warranted in light of that prospect."
  - Ds clearly rebut presumption if they show that payment was no more than an amount commensurate with avoided litigation costs
    - Considerable leeway in comparing payment to avoided costs (e.g., can factor in costs of business disruption)
  - If payment greatly in excess of avoided costs, did terms of settlement eliminate possibility of competition prior to expiration of patent?
    - Ds can overcome presumption by showing that avoiding Patent Act's procedures for excluding alleged infringers did not depart from balance struck in Patent Act
    - Ds must show that despite payment, agreed-upon entry date and other terms reflected their contemporaneous evaluations of likelihood that a judgment would have resulted in generic competition before patent expired