BATES WHITE HEALTHCARE LAW AND ECONOMICS WORKSHOP

SETTING THE FRAMEWORK: ANTITRUST REVIEW OF REVERSE-PAYMENT PATENT SETTLEMENTS

Seth C. Silber
Wilson, Sonsini, Goodrich & Rosati
October 29, 2009

A Decade of Reverse-Payment Settlements

Late 90's	• FTC first begins investigating pharmaceutical settlements
2000-2001	• FTC consents in *Terasozin* and *Cardizem* (interim settlements)
2003	• FTC decision in *Schering* (settlement violated FTC Act)
2003	• Congress enacts MMA filing requirement
2005	• 11th Circuit reverses FTC decision in *Schering* • 2d Circuit upholds settlement in *Tamoxifen*
2006	• Supreme Court denies cert in *Schering* • Senators Leahy and Kohl introduce "ban" legislation
2008	• Fed Circuit upholds settlement in *Ciprofloxacin*
2009	• Senate and House legislation passes out of relevant Committees

Current Review Regime: MMA Patent Settlement Filing Requirement

- Pharmaceutical patent settlements required to be filed with FTC (per 2003 Medicare Modernization Amendments)
  - Brand-generic patent settlements involving Paragraph IV Hatch-Waxman litigation, and
  - Agreements that relate to the marketing of generic product or to the 180-day exclusivity period

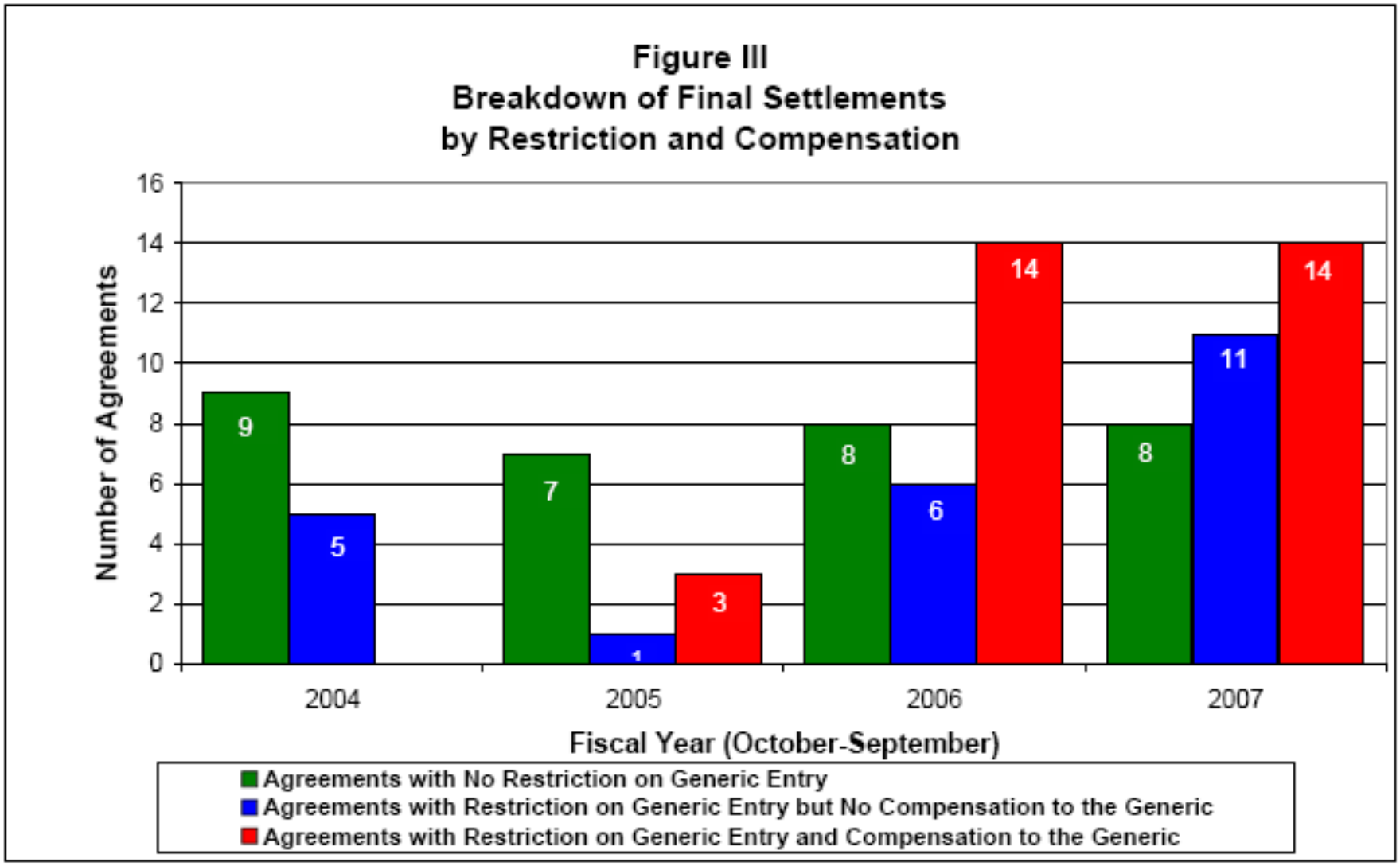
- Filing Regime Only Provides *NOTICE* to FTC
  - NOT approval
  - No waiting period (like HSR regime)
  - BUT lack of FTC inquiry doesn't mean FTC cannot challenge later

- Why Congress Enacted This Requirement
  - Waxman: "to re-emphasize the Hatch-Waxman Act's original intent of enhancing competition, not collusion, between generic and name-brand drug manufacturers"

FTC Patent Settlement Reports: Notification Regime Provides Data on Relevant Conduct

- **FY 2004 Report**
  - "Red Flag" Period (2000-2004): FTC consents and FTC *Schering* Decision
  - *0* of 14 settlements had payment and restriction on generic entry
- **FY 2005 Report**
  - Following 11th Circuit opinion in *Schering*
  - *3* of 16 settlements had payment and restriction on generic entry
- **FY 2006 Report**
  - Following 2d Circuit opinion in *Tamoxifen*
  - *14* of 28 settlements had compensation
    - Ten agreements with "side deals" where compensation to generic for rights not related to product at issue, and generic agreed to entry date
- **FY 2007 Report**
  - *14* of 33 settlements had compensation
    - Three agreements with "side deals"
    - Eleven agreements where brand agrees not to launch authorized generic during exclusivity period

FTC FY 2007 Patent Settlement Report



Legislation on Patent Settlements: H.R. 1706

- Status
  - Rush/Waxman – introduced March 25, 2009
  - Passed out of House Energy & Commerce Committee on July 31, 2009 as amendment to omnibus health care reform legislation
- Key Provisions
  - Bans payment of "anything for value" to generic in exchange for restriction on generic entry
  - Allows for settlements where:
    - Only a patent split (no compensation)
    - Waiver of patent damages based on prior marketing of drug
  - FTC Rulemaking to exempt certain agreements FTC "finds in furtherance of market competition and for the benefit of consumers"
  - Certification with MMA filing by senior company official that all agreements have been submitted

Legislation on Patent Settlements: S. 369

- Status
  - Introduced originally in 2006 with provisions nearly identical to H.R. 1706
  - Substitute introduced by Sen. Kohl in September 2009
  - Passed out of Senate Judiciary Committee on October 15, 2009

- Key Provisions
  - FTC may initiate proceedings regarding settlements:
    - Presumption of anticompetitive effects if "anything of value" to generic in exchange for restriction on generic entry
      - FTC factual findings are "conclusive" upon appellate review
    - Exception: Presumption shall not apply if parties show clear and convincing evidence that procompetitive benefits outweigh anticompetitive effects
      - Factors to consider set forth (e.g., patent split, amount of consideration)
      - Factors FTC shall not presume set forth (e.g., entry before expiry is procompetitive)
  - Other Key Provisions
    - Exclusions: (1) just patent split; (2) $7.5 million payment; (3) covenant not to sue
    - Appellate Review: D.C. Circuit or home Circuit of NDA or ANDA holder
    - Civil Penalty: up to 3 times the "value received by the party" attributable to violation
    - FTC Rulemaking may exempt certain agreements (similar to H.R. 1706)
    - Certification with MMA filing (similar to H.R. 1706)
    - Statute of Limitations on FTC Action: 3 years from date of MMA filing

Models for Antitrust Review of Patent Settlements

- **No Regime At All**
  - This was situation pre-MMA (2000-2003)
  - No filing requirement or "ban" needed because FTC enforcement had strong deterrent effect
- **Notification Regime**
  - This is current situation under MMA
  - Deterrent effect relies upon:
    - FTC willingness/resources to investigate/litigate cases
    - Whether FTC/private parties are "winning" legal battle in the courts
  - At present, deterrent effect varies greatly from company to company
- **Presumption of Effects & Enhanced FTC Litigation Authority**
  - This is the current Senate (S. 369) legislation
  - Deterrent effect substantially enhanced over current "notification" regime
- **Per Se Treatment or "Ban"**
  - This is the current House (H.R. 1706) legislation
  - A "ban" or near "ban" is obviously greatest deterrent
  - Industry has pushed back arguing this is an over-deterrent

Interim Authorized Generic Report Issued June 2009: Competitive Implications of Authorized Generics

- **Short-Term:**
  - Retail drug prices 4.2% lower and wholesale prices 6.5% lower when an AG competed with first-filer generic during 180-day exclusivity period
  - Revenues for first-filer generic reduced by 47-51% when it faced competition from an AG during the 180-day exclusivity period.
- **Long-Term:**
  - Report did not provide empirical analysis into whether AGs reduce the incentive of generic firms to pursue generic products.
  - Report states, however, that the "impact of AG entry likely changes the calculus of business decision-making for both the generic and brand firms. These impacts will be explored in the final report."

Interim Authorized Generic Report Issued June 2009:

- **Patent Settlements with Authorized Generic Provisions**
  - Facing large revenue loss from AG entry, generic may delay launch in return for brand's agreement not to market AG during generic's 180-day exclusivity period.
  - About 25% final settlements with first-filers included brand promise to withhold AG
    - resulted in deferred entry in those cases by 34.7 months on average
  - Such agreements can cause consumer harm by
    - delaying generic entry and the accompanying price discounts
    - eliminating price competition from AG during generic's 180-day exclusivity
- **Leibowitz Statement on Authorized Generic Report**
  - "Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, 'if you go away for several years, I'll give you $200 million.' Now, the brand might say to the generic, 'if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG.' This use of AGs is not only simple, it's inexpensive – a relatively low-cost way for a brand to preserve its monopoly and its high profits along with it."