Antitrust Developments – 2015: Developments in the FTC's Enforcement and Private Antitrust Litigation

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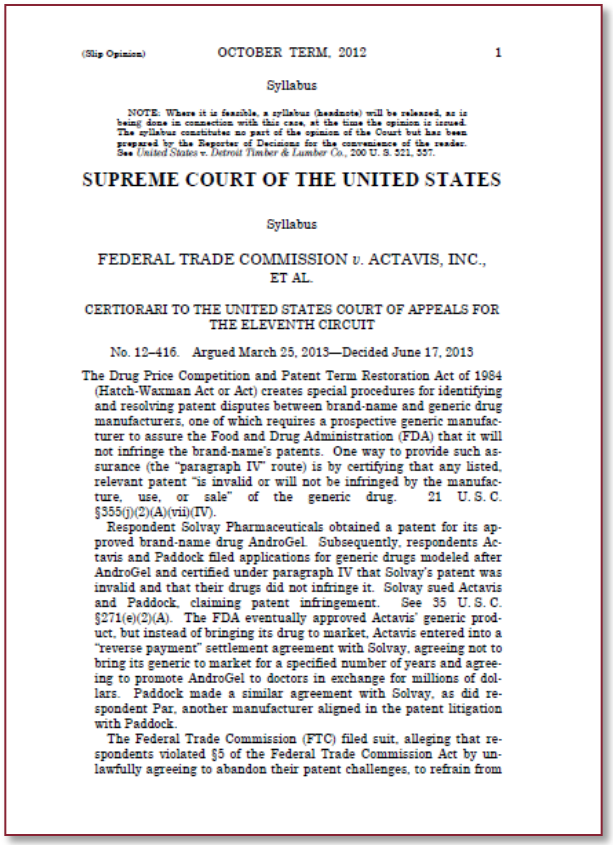
Overview

- Settlements in the wake of *Actavis*
  - Defining "large and unexplained," burden shifting, non-cash payments
  - How reasonable is the post-*Actavis* "rule of reason"?
- *Namenda* and the developing "product hopping" standard
  - Is *Namenda* consistent with antitrust principles, and does it adequately preserve innovation incentives?
  - Supporting next generation products post-*Namenda*
- REMS restrictions and direct sales to generics
  - What is the state of the law, and what can innovators do in response to requests for samples?

Actavis Developments



(Slip Opinion) OCTOBER TERM, 2012 1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

FEDERAL TRADE COMMISSION *v.* ACTAVIS, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 12–416. Argued March 25, 2013—Decided June 17, 2013

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act or Act) creates special procedures for identifying and resolving patent disputes between brand-name and generic drug manufacturers, one of which requires a prospective generic manufacturer to assure the Food and Drug Administration (FDA) that it will not infringe the brand-name's patents. One way to provide such assurance (the "paragraph IV" route) is by certifying that any listed, relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug. 21 U. S. C. §355(j)(2)(A)(vii)(IV).

Respondent Solvay Pharmaceuticals obtained a patent for its approved brand-name drug AndroGel. Subsequently, respondents Actavis and Paddock filed applications for generic drugs modeled after AndroGel and certified under paragraph IV that Solvay's patent was invalid and that their drugs did not infringe it. Solvay sued Actavis and Paddock, claiming patent infringement. See 35 U. S. C. §271(e)(2)(A). The FDA eventually approved Actavis' generic product, but instead of bringing its drug to market, Actavis entered into a "reverse payment" settlement agreement with Solvay, agreeing not to bring its generic to market for a specified number of years and agreeing to promote AndroGel to doctors in exchange for millions of dollars. Paddock made a similar agreement with Solvay, as did respondent Par, another manufacturer aligned in the patent litigation with Paddock.

The Federal Trade Commission (FTC) filed suit, alleging that respondents violated §5 of the Federal Trade Commission Act by unlawfully agreeing to abandon their patent challenges, to refrain from

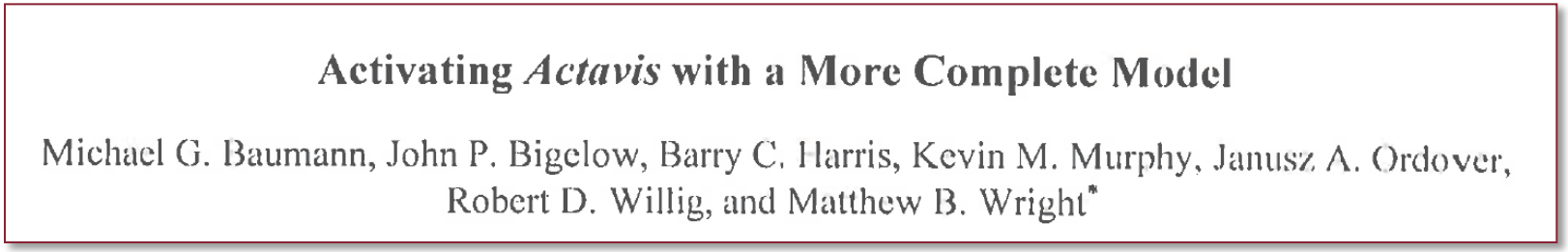
Actavis in a nutshell:

- "Reverse payment" case subject to the "rule of reason"
- No antitrust immunity even within the "scope of the patent"
- "Large, unexplained" payments carry risk of anticompetitive effect
- Explanations include litigation cost avoidance and fair value for goods/services
- Structure of rule of reason left to the district courts

Actavis Developments

Current battlegrounds

"Large" and "Unexplained"/"Unjustified" – competing economic framework:



Actavis Developments

Current battlegrounds

Which party has the burden of proving a payment is fair value or not?

- Standard rule of reason framework: (1) plaintiff must prove anticompetitive effects, (2) defendant may offer potentially off-setting procompetitive justifications, (3) plaintiff must show (a) benefits are pretext or (b) anticompetitive harm outweighs benefits
- *Actavis* ambiguity:
  - "[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, … its independence from other services for which it might represent payment"
  - "An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present"

Actavis Developments

Current battlegrounds

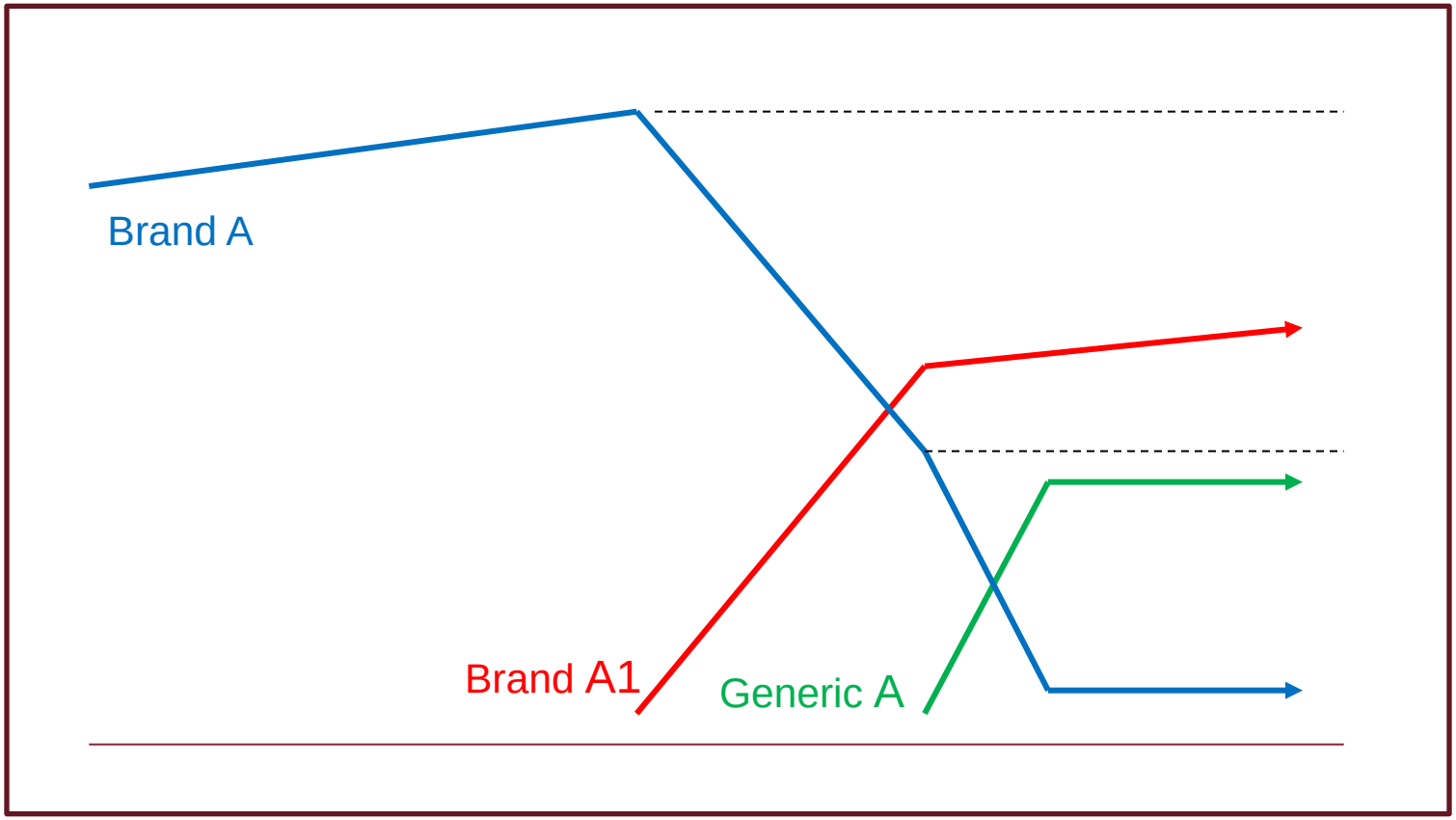
- Significant district court decisions:
  - *Nexium* (D. Mass.) – jury instructions placed burden on plaintiffs to prove a large, unexplained payment
  - *Provigil* (E.D. Pa.) – summary judgment decision held that plaintiffs must prove “large” (>litigation costs), defendants must prove “fair value”

Actavis Developments

Current battlegrounds

- Are non-cash payments subject to “rule of reason”
  - E.g., “no-AG” agreements, debt forgiveness
- Initial split among district courts, but Third Circuit recently confirmed non-cash “payments” subject to same standard in *Lamictal*:
  - No-AG provisions bring promise of increased revenue during 180-day exclusivity period
  - Significant monetary value capable of inducing generic to drop patent challenge that might otherwise result in greater competition
  - Fact that exclusive license is contemplated by Patent Act does not permit use of licenses to induce delay

“Product Hopping”

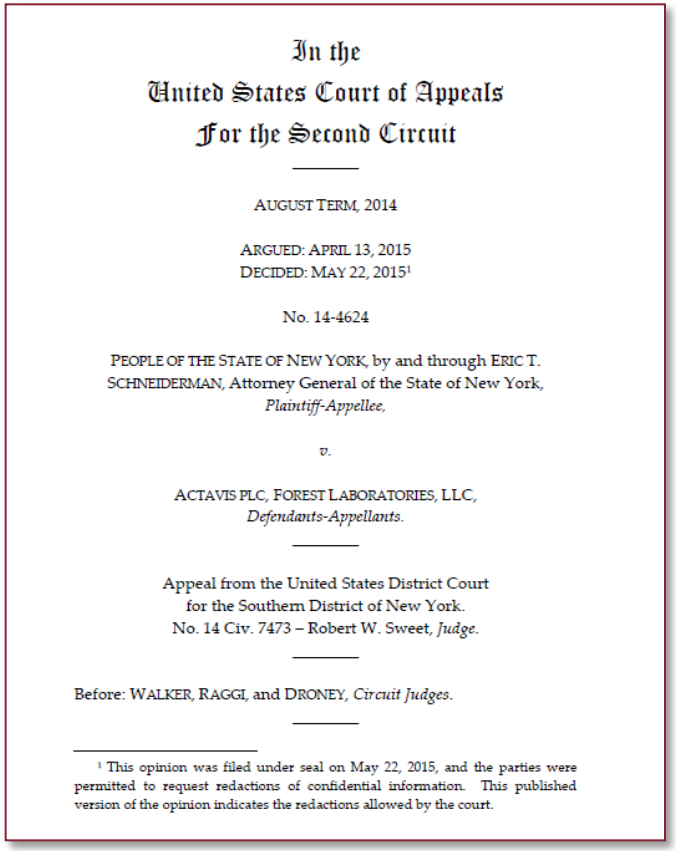


“Product Hopping”

A brief history—the “coercion” standard

- *TriCor* (D. Del. 2008) – market withdrawal of legacy products and replacement with next generation (with allegedly meaningless change) states monopolization claim.
- *Nexium/Prilosec* (D.D.C. 2008) – launch and promotion of next generation product in advance of generic entry not exclusionary because consumer choice determined market outcomes.
- *Suboxone* (E.D. Pa. 2014) – announced withdrawal of legacy combined with alleged disparagement of legacy’s safety sufficient to state a claim.

"Product Hopping"



In the
United States Court of Appeals
For the Second Circuit

AUGUST TERM, 2014

ARGUED: APRIL 13, 2015
DECIDED: MAY 22, 2015[1]

No. 14-4624

PEOPLE OF THE STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,
Plaintiff-Appellee,

v.

ACTAVIS PLC, FOREST LABORATORIES, LLC,
Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of New York.
No. 14 Civ. 7473 – Robert W. Sweet, *Judge.*

Before: WALKER, RAGGI, and DRONEY, *Circuit Judges.*

[1] This opinion was filed under seal on May 22, 2015, and the parties were permitted to request redactions of confidential information. This published version of the opinion indicates the redactions allowed by the court.

Namenda in a nutshell:

- Product innovation is subject to rule of reason
- "Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition" *cf Berkey Photo*
- Limited distribution (hard switch) deprived consumers of choice between products
- Impeding operation of state substitution laws is actionable anticompetitive effect

“Product Hopping”

Namenda conclusions/assumptions

- State substitution laws implemented because “pharmaceutical market is not a well-functioning market”—the price disconnect
- Insufficient market forces consumers to available generics without automatic substitution
- Interfering with most efficient means of distribution is exclusionary under Section 2
- Antitrust laws may be employed to bolster state substitution laws

“Product Hopping”

Namenda and innovation incentives

- Importance of incremental innovation in pharmaceutical industry
- Incremental innovation is costly and risky
- Impact of “barriers to exit” on pharmaceutical innovation incentives
- Impact of insulating generics from competition from improved products on innovation incentives
- Unique harm caused by injunctions requiring innovators to sell and support legacy products

“Product Hopping”

Spectrum of Conduct under *Namenda* standard

- Pre-generic launch of next generation product
- Complete shift of sales and promotional efforts to new product
- Creation of price incentives
- Limited distribution of legacy product
- Withdrawal of legacy product

REMS and ANDA filers

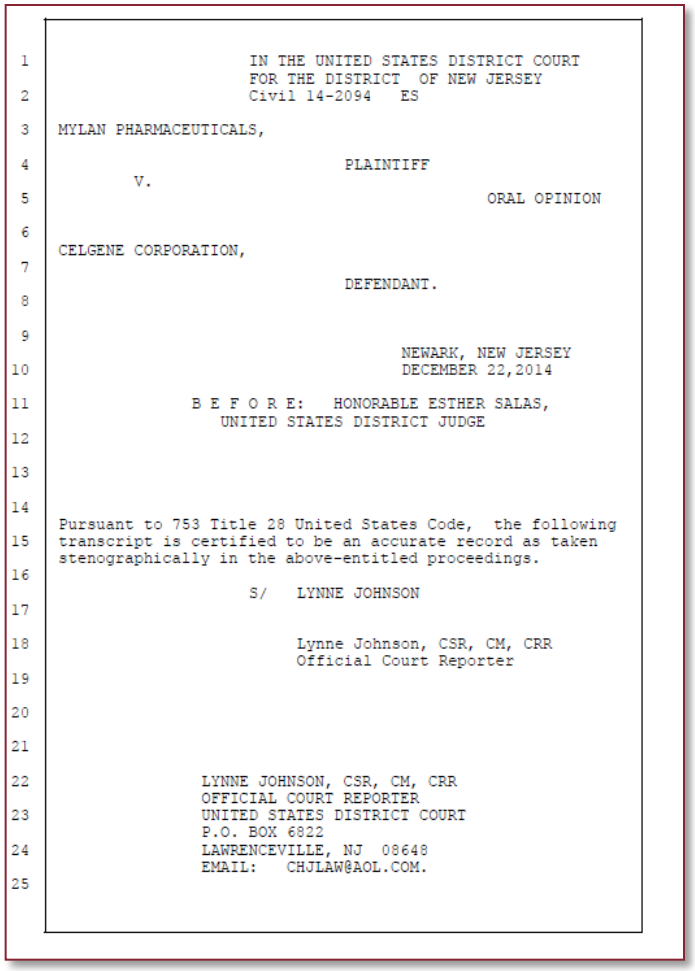
- FDA REMS guidelines often limit distribution of innovator drugs (e.g., to and through qualified pharmacies)
- ANDA filers forced to ask innovators to provide samples for bioequivalence testing (typically acquire through wholesalers)
- Claim refusal to sell is unlawful monopolization
  - FTC has filed amicus briefs in support of generics, arguing refusal to sell at list price to generics would be irrational but for the exclusion of competition

REMS and ANDA filers

Antitrust Duty to Deal

- General rule – No affirmative duty to deal
- Exception *(Aspen Skiing, Trinko):*
  - (1) there is a prior course of dealings between the parties; and
  - (2) the alleged monopolist irrationally forsook short-term profits for long-term anticompetitive gain – "no economic sense"
- Dispute: whether (1) is necessary, or whether claim may turn on "no economic sense" even if no prior course of dealing

REMS and ANDA filers



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Civil 14-2094 ES

MYLAN PHARMACEUTICALS,

PLAINTIFF

V.

ORAL OPINION

CELGENE CORPORATION,

DEFENDANT.

NEWARK, NEW JERSEY
DECEMBER 22,2014

B E F O R E: HONORABLE ESTHER SALAS,
UNITED STATES DISTRICT JUDGE

Pursuant to 753 Title 28 United States Code, the following transcript is certified to be an accurate record as taken stenographically in the above-entitled proceedings.

S/ LYNNE JOHNSON

Lynne Johnson, CSR, CM, CRR
Official Court Reporter

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Mylan v. Celgene (D.N.J.):

"The Third Circuit cases to consider the scope of the 'no duty to deal' do not appear to adopt a strict requirement that a party must plead 'prior course of dealing' for its claims to proceed…
To the contrary the cases in our Circuit that have considered the scope of the affirmative duty to deal suggest that 'prior course of dealing' is relevant but not dispositive in determining whether such a duty applies."

REMS and ANDA filers

To be continued…

- REMS challenges within circuits that have required prior course of dealing
- Insisting upon FDA assurance that generics protocols comply with REMS, and sale will not violate REMS (see December 2014 guidance)
- Refusal based on safety and liability concerns

Questions?

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