

From PLI's Program
Pharmaceutical Patents & Competition Policy:
How to Pass Muster with the FTC
#5529



The Ftc's Pharmaceutical Cases

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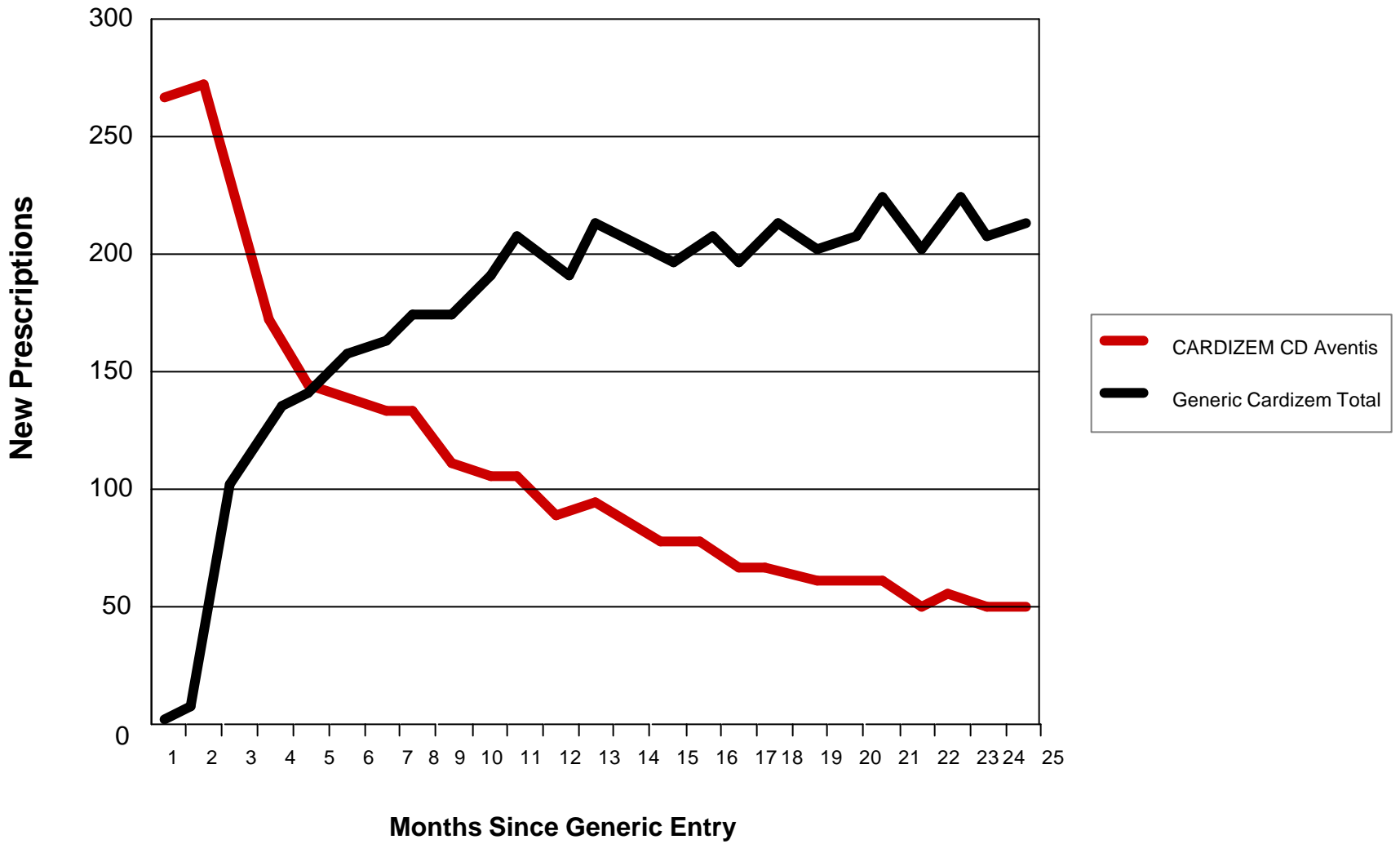
Types of Pharmaceutical Cases

- **Patent Litigation Settlements**
- Patent Listings in the FDA's "Orange Book"
- Acquisitions of Exclusive Rights to Patents
- Actions by Generics Affecting Generic Competition
- Drug Company Mergers

Price Effects of Generic Entry

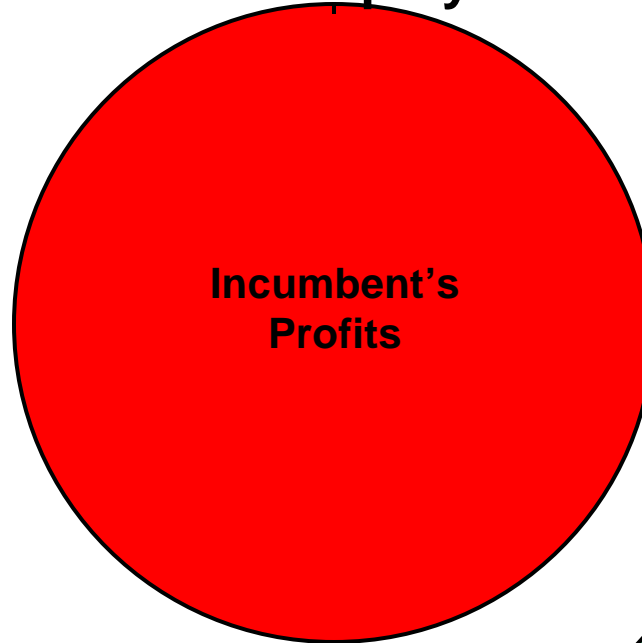
- First generic enters at 75% of brand's price and takes 50% of sales within a year
- Subsequent generic entrants compete price down further
- A Congressional Budget Office report estimated that consumers saved \$8 to \$10 billion at retail pharmacies in one year alone by purchasing generics

Generic Cardizem Entry



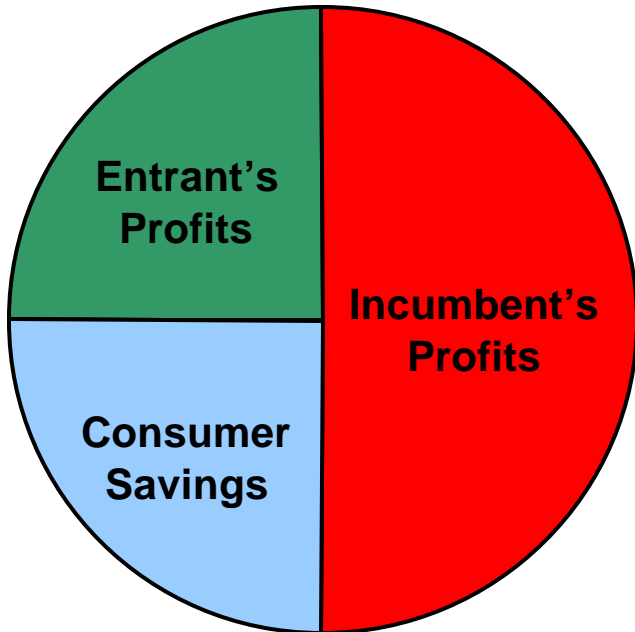
Incentives to Pay for Delay

Monopoly



Incumbent's Profits

Competition

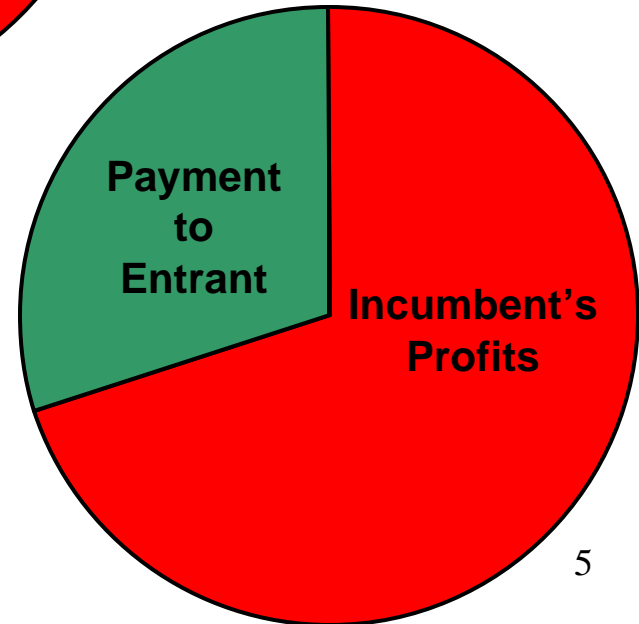


Entrant's Profits

Incumbent's Profits

Consumer Savings

Retained Monopoly



Payment to Entrant

Incumbent's Profits

Goals of the Hatch-Waxman Act

- Maintaining incentives to develop new drugs
- Increasing availability of lower-priced generic drugs

Hatch-Waxman Act Provisions at Issue in FTC Cases

- Patent Listing
- Paragraph IV Certification
- 30-Month Stay
- “First Filer” & 180-Day Exclusivity

Patent Listing

- NDA holder shall list any patent in FDA's "Orange Book" that:
 - (1) "claims the drug . . . or a method of using the drug"
 - (2) "with respect to which a claim of patent infringement could reasonably be asserted"
- Purpose: Puts world on notice of patents that cover a drug

Paragraph IV Certification

- Company that wants to sell a generic prior to brand's patent expiration must provide written notice that the patent is invalid or not infringed to FDA, NDA holder, and patent owner
- Purpose:
 - Puts NDA holder and patent owner on notice
 - Creates a statutory act of infringement

30-Month Stay

- Branded company has 45 days to evaluate the Paragraph IV certification
- If branded company files a patent infringement suit within the 45 days, FDA is automatically stayed from approving the generic for 30 months
- No showing of likelihood of success is necessary
- Purpose: Provides the parties time to resolve the litigation

“First Filer” & 180-Day Exclusivity

- First generic to file an ANDA with a Paragraph IV certification is given 180 days of generic marketing exclusivity
- 180-day exclusivity period is triggered by:
 - First commercial marketing of the generic
 - Court decision declaring brand’s patent invalid or not infringed
- Purpose: Provides generics with incentives to invent around or challenge invalid patents

Patent Litigation Settlement Cases

- Parties enter into an interim or final settlement
- Generic agrees to refrain from going to market until a date certain
- Settlement includes payment or other consideration from the brand to the generic
- Settlement may include agreements that generic:
 - Will not go to market with any non-infringing product
 - Will not relinquish its rights to the 180-day exclusivity

FTC's "Settlement Cases"

Abbott/Geneva -- Consent order

Hoechst/Andrx -- Consent order

Bristol-Myers Squibb (BuSpar) -- Consent order

***Schering/Upsher-Smith/AHP* – Trial, FTC decision on full record; holding that settlements were anticompetitive**

Settlement Case “Red Flags”

- Payments from patent holder to alleged infringer
- Restrictions on generic’s entry with non-infringing products
- Restrictions on generic’s ability to relinquish 180-day exclusivity

Companies raise the patent laws as a defense in the settlement cases

- Assert they are merely exercising their rights under the patent laws to exclude infringers
- Seek to turn antitrust case into patent actions, by requiring the FTC to prove the patent is invalid or not infringed

FTC's *Schering* Decision: Brand-generic settlements were anticompetitive

- “[S]ufficient proof of adverse anticompetitive effects.” *Schering* at 10
 - Schering and Upshur expected generic entry to erode Schering’s sales substantially; these expectations consistent with empirical observations of generic entry effect on brand sales. *Schering* at 19, 21.
 - Upsher’s actual entry in September 2001 confirmed these expectations: rapid decline in Schering brand sales and growth in lower-priced Upsher generic sales. *Schering* at 22.

Schering

- Absent offsetting proof, “it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.” *Schering* at 26.
- “The resulting adverse effects on consumers are obvious” when patent holder and generic agree to defer generic entry and split patent holder’s profit. *Schering* at 27.

Schering

- “[I]t is not necessary to inquire into the merits of the underlying patent disputes.” *Schering* at 10
 - Brand’s presumptively valid patent did not necessarily confer right to exclude generic entry. *Schering* at 30.
 - Antitrust tribunal’s focus should be “on the state of the world as it was perceived by the parties at the time they entered into the settlement agreement, when they could not be sure how the litigation would turn out.” *Schering* at 32.
 - Antitrust tribunal’s after-the-fact inquiry into merits of underlying litigation likely to be unhelpful and unreliable, and is unnecessary. *Schering* at 34-35.

Schering

- “[T]he parties have not proved their ancillarity defenses.”
Schering at 10
 - Public benefit in settling litigation insufficient justification for payments to delay generic entry; no record evidence to support Schering’s various “after-the-fact rationalizations.” *Schering* at 36-39.
- “[T]he payments from the pioneer to the generics were, in whole or in substantial part, consideration for delay rather than for products licensed from the generic.”
 - Evidence undermines Schering’s assertion that \$60 million payment was in full for licenses received from Upsher. *Schering* at 39 et seq.

Impact of Settlement Cases?

