Antitrust and Competition: Life Sciences

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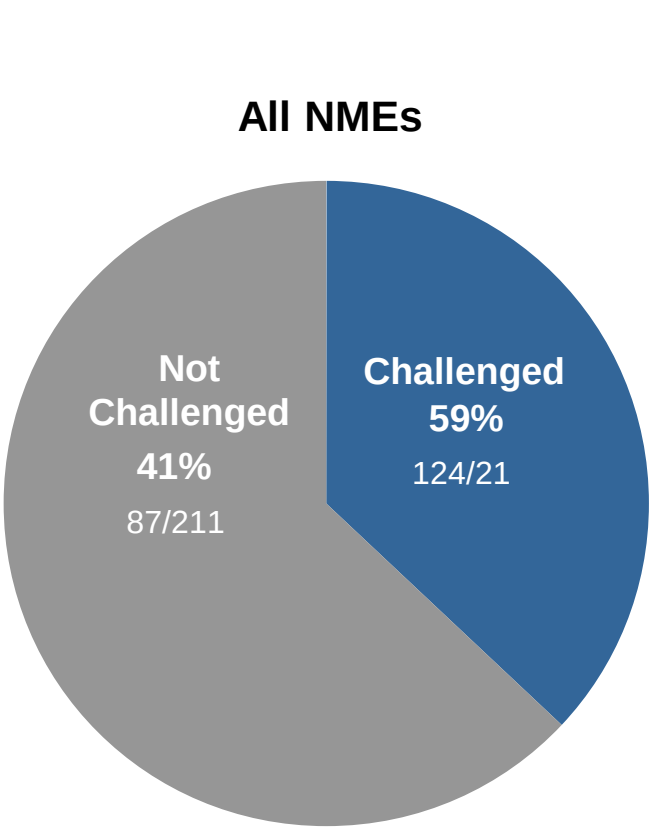
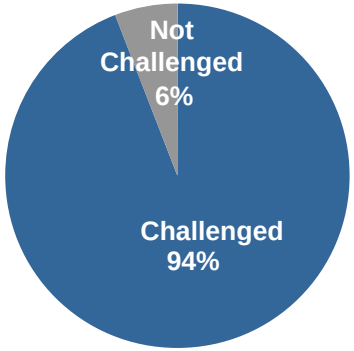
Agenda

- Hatch-Waxman settlements and reverse payment developments
- The latest on antitrust claims arising from “product hopping”
- Revisions to DOJ/FTC IP licensing guidelines, and a primer on market definition for pharmaceuticals

Higher Selling Drugs Attract Patent Challenges

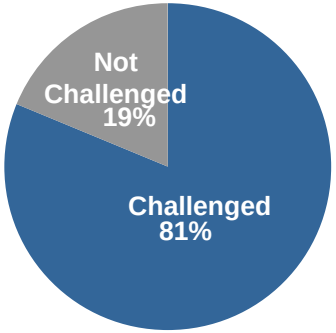
(NMEs Approved 1994 – 2006)

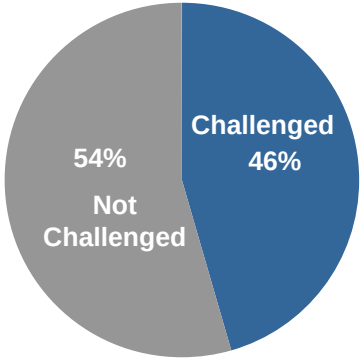




Greater than $1B

Between $1B and $500M

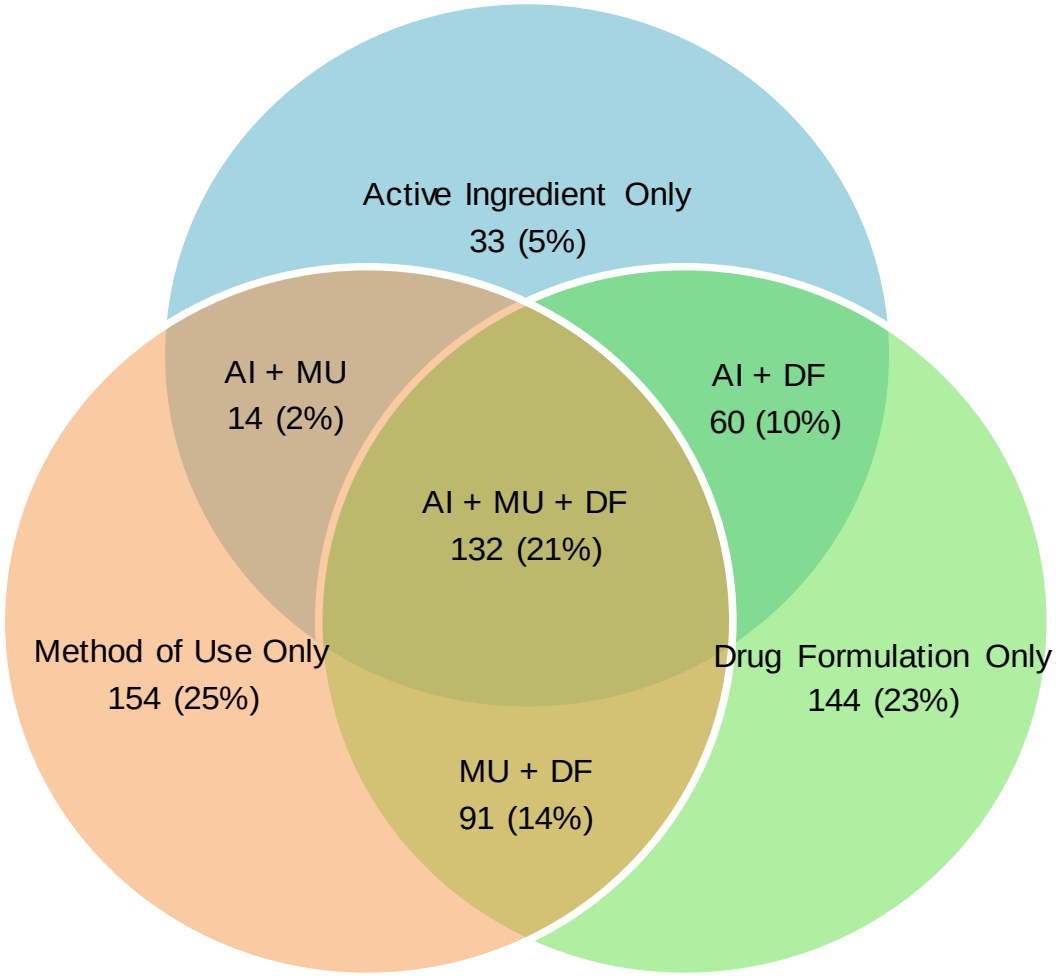




Less than $500M

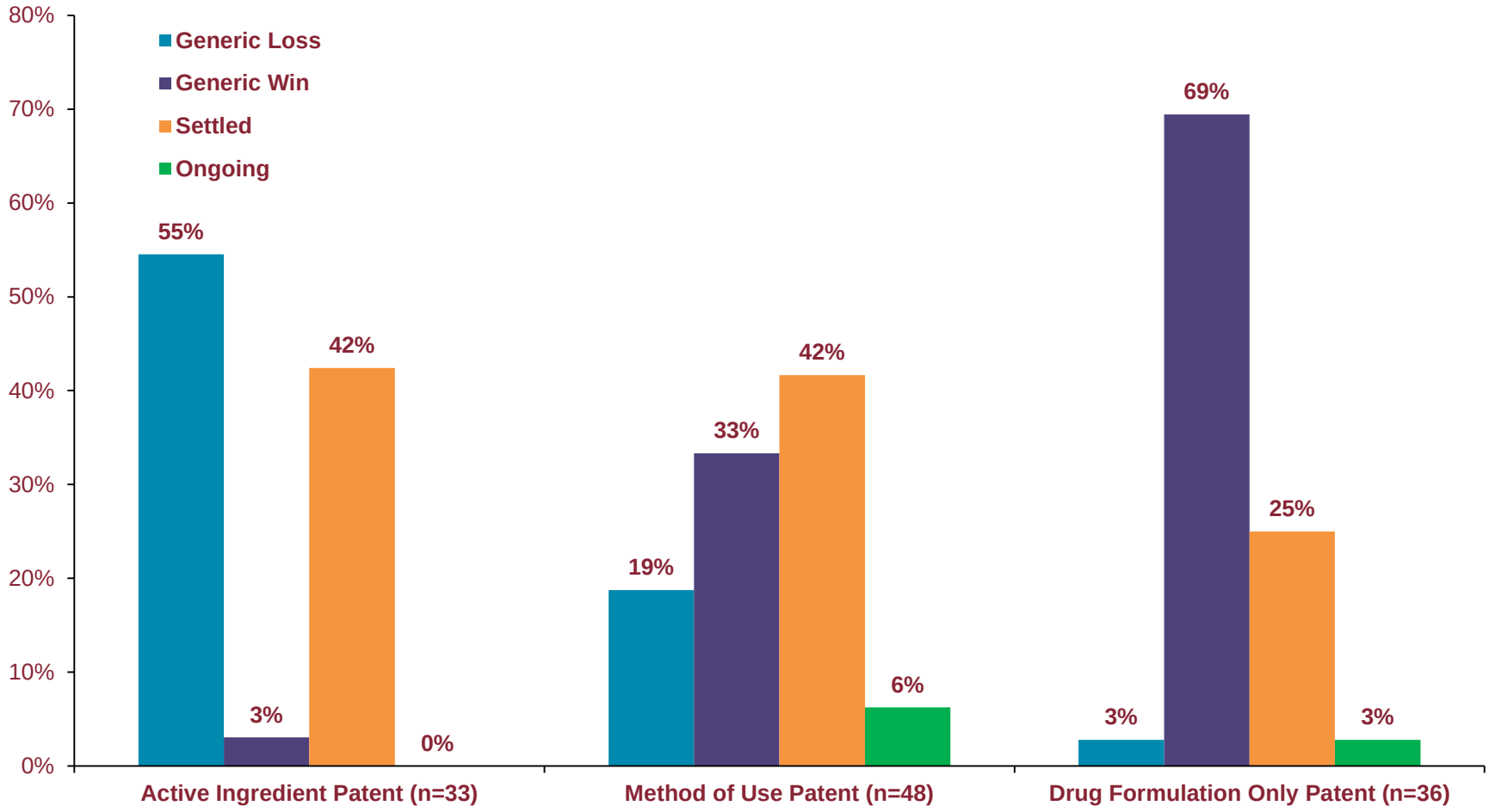
Patents Challenged

(628 Patents) Orange Book listed Patents, 1994 – 2006 NMEs



Outcomes of Patent Challenges

(Top Quintile NMEs 1994 – 2006)



Reverse Payment Developments

Recent developments

- Most litigated issues in the wake of *Actavis*
  - Non-cash payments
  - Burdens of proof, available justifications
  - Relevance of patent merits
- *Lamictal* (3d Cir. June 2015)
  - "No-AG" agreements constitute reverse payments subject to *Actavis* framework
  - June 6, 2016 - SCOTUS invites input from solicitor general
- *Wellbutrin* (E.D. Pa. Sept. 23, 2015)
  - Potential pro-competitive effects of reverse payments settlements include more than just explanations for reverse payments
  - Private litigants must prove that, but for the settlements, generic entry would have been sooner
  - Currently on appeal to the Third Circuit, argument held Sept. 7, 2016

Reverse Payment Developments

Proposed stock price proxy for anticompetitive effects, causation, and damages

- Drake et al. (2015): Positive stock price reaction to an announcement of Paragraph IV settlement is an indicator of a generic entry delay in a “reverse payment” settlement
  - In settlements with reverse payments, abnormal stock price return for a branded company was approximately 6% at the time of the announcement
  - Authors interpret this return as investors’ valuing the “extra” profits due to the brand maintaining its monopoly position for longer than what would have been expected with litigation
- Can these “extra” profits be explained by factors other than delay in generic entry?

Reverse Payment Developments

What factors may explain positive stock price reaction to a settlement announcement?

- Managerial risk aversion
- Business costs created by litigation uncertainty
  - Cash flows often used to finance R&D; if uncertain, company may choose to undertake less risky R&D projects with lower expected payoffs
- Costs associated with disruptions to revenues
  - Abrupt loss of revenues can generate costs, e.g., cost of laying off (and later re-hiring) sales force or scientific personnel
- Branded company may wish to pay a generic challenger to avoid such costs – *even when* agreeing to the expected generic entry date
  - These costs are higher, *and reverse payments are more frequent*, for more "important" drugs (drugs whose sales constitute a large proportion of the branded company revenues)
  - "Importance" – and not the presence of a "reverse payment" – explains positive stock price reaction

Product Hopping

Recent developments

- Will soft-switch/hard-switch distinction become prevailing standard?
- *Namenda* (2d Cir. 2015)
  - "Hard switches" subject to rule of reason analysis
  - "Crosses the line from persuasion to coercion"
  - Competition through state substitution laws is the only cost-efficient means of competition for generics
  - "Free riding" by generics is "authorized by law"
- *Doryx* (E.D. Pa. Apr. 16, 2015)
  - Granted summary judgment for failure to present plausible evidence of monopoly power (more on that later)
  - "Switch" to new Doryx formulations not anticompetitive because it did not impede generics' ability to compete
  - "Mylan … seeks to transform its own refusal to incur promotional costs into Defendants' anticompetitive conduct"
  - Currently on appeal to the Third Circuit, argument held July 14, 2016

DOJ/FTC IP Guidelines Update

DOJ and FTC to update *Antitrust Guidelines for the Licensing of Intellectual Property*

- Guidelines provide antitrust enforcement principles for licensing transactions (e.g., cross-licensing; exclusive licensing)
- First revision in more than 21 years
- Public comments due September 26

Few substantive changes, but one proposal is noteworthy for pharma

- New “Research and Development Market” framework
- Would replace existing “Innovation Market” concept
- Likely to apply mainly in pharma transactions

How does the “R&D Market” framework fit into the bigger picture?

Market Definition: Background

Why relevant?

- Framework used by agencies and courts to assess anticompetitive effect of conduct or transaction
  - Does the defendant have a monopoly? (*Doryx*)
  - Do the conspiring defendants have market power?
  - Will an acquisition substantially lessen competition?
  - Does a licensing transaction impair competition?

Three types of markets

- Products that are interchangeable for each other
  - E.g., *Zyvox, Cubicin*, *Vibativ*, *Vancomycin*
- Technologies that are interchangeable for each other
  - (Often patented) R&D results
- Research & Development aimed at commercializable products
  - E.g., *Amgen/Immunex* (2002) (R&D for cytokine inhibitors)

Market Definition: Approach

Traditional price increase test

- "If the price for product A were to increase by 5-10%, which products would consumers switch to?" (FTC/DOJ SSNIP test)

Pharmaceutical market definition

- Can be tricky because price increase tests don't always work
  - Physicians select drugs but are (relatively) insensitive to price
  - Patients lack expertise and (often) don't pay out of pocket
  - Payors have no direct involvement in prescription decisions
  - Many transactions involve drugs in development
  - Other issues (e.g., generic v. branded competition; off-label use) muddy the waters even further

Market Definition: Agency Practice

No clear agency guidelines

- Extensive precedent, mostly from the FTC, but approaches to market definition vary greatly
- Factors include active ingredient; indications and off-label uses; mechanism of action; relative safety and efficacy profiles

Examples:

Approach	Case	Market
Indication	Pfizer/Warner-Lambert (2000)	• Research, development, manufacture, and sale of drugs for treatment of Alzheimer's
Mechanism of Action	Amgen/Immunex (2002)	• TNF inhibitors and IL-1 inhibitors
Compound	Teva/Cephalon (2011)	• Human pharmaceutical products containing modafinil

Market Definition: Agency Practice (Cont'd)

Key question: what are the closest competitors to the drugs at issue?

May need to consider multiple factors

- Example: *Actavis/Durata* (2014)

Consideration	Durata	Actavis
Indication	Acute Bacterial Skin and Skin Structure Infections (ABSSSI)	
Compound	Dalbavancin	Ceftaroline
MOA	PG chain elongation inhibitor	PBG cross-link inhibitor
Dosage	1/week for two weeks	1/day
Primary use	Outpatient	Inpatient

Litigating Market Definition

General principles

- Treatment protocols / medical experts identify therapeutic alternatives
- Formulary treatment and negotiations are key
- Cases often turn on brand's marketing, sales, and pricing analyses

Doryx (E.D. Pa. 2015), currently on appeal to Third Circuit

- Granted summary judgment for defendant on monopolization claim, holding Plaintiffs could not establish a Doryx-only product market
- Physicians treated Doryx and other acne medications as interchangeable; FDA labeling on other acne medications similar; formularies encouraged doctors/patients to try cheaper alternatives

Questions?

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