Drug Patents and Competition Law

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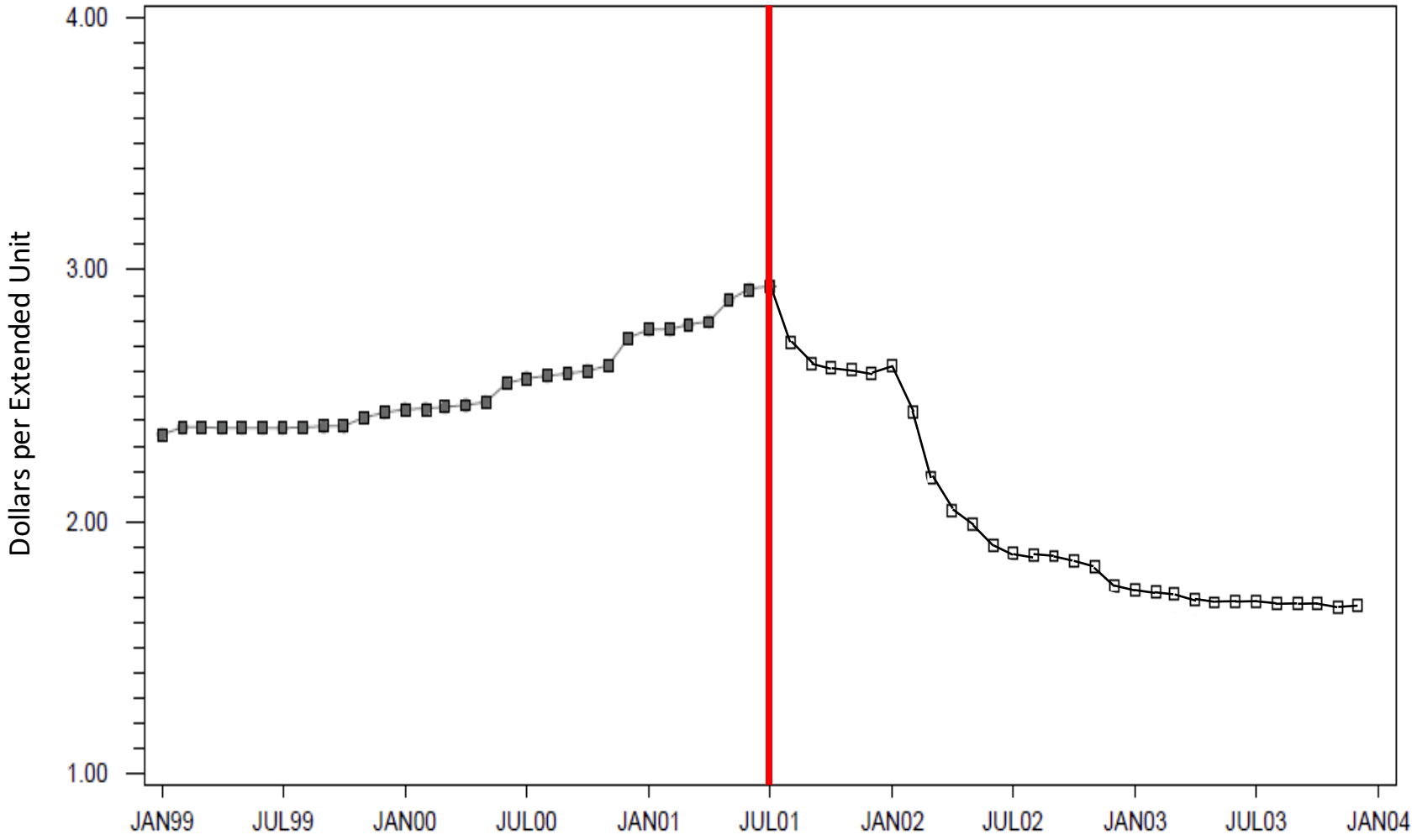
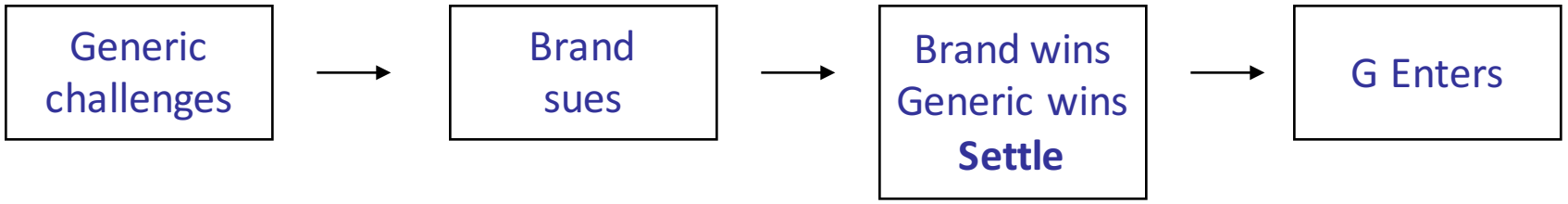
EARLY GENERIC ENTRY

Average price of fluoxetine before and after generic entry



Source: Frank and Hartman (2009)

THE ISSUE



"Company [B] sues Company [G] for patent infringement.

The two companies settle under terms that require

(1) Company [G], the claimed infringer, not to produce the patented product until the patent's term expires, and

(2) Company [B], the patentee, to pay [G] many millions of dollars."

Actavis (Supreme Court 2015)

THE STAKES

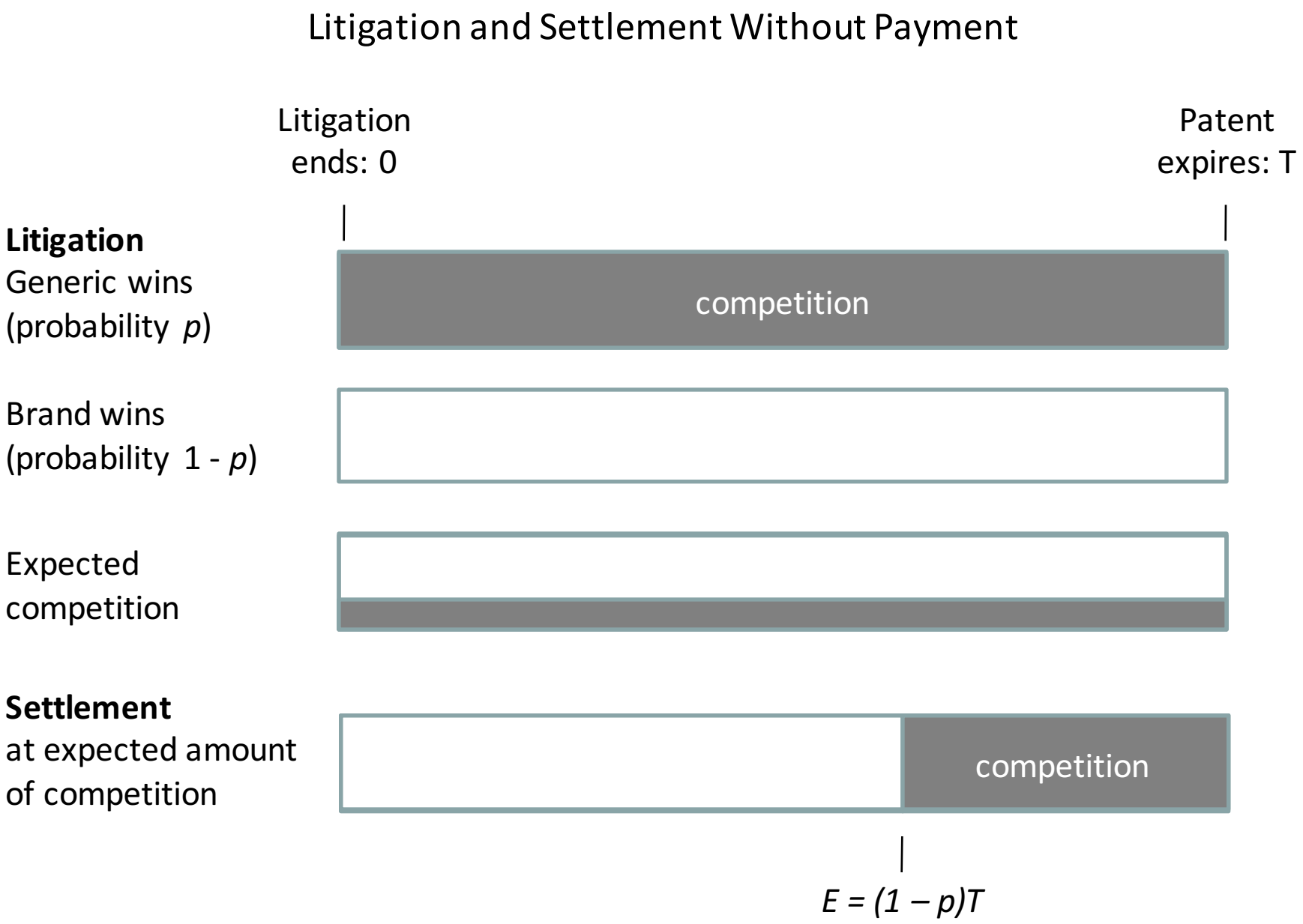
Reverse Payment Litigation in the United States

Year of first settlement	Active ingredient (brand name)
1997	Ciprofloxacin (Cipro)
	Potassium chloride (K-Dur)
2005	Metaxalone (Skelaxin)
	Modafinil (Provigil)
	Niacin (Niaspan)
	Lamotrigine (Lamictal)
	Venlafaxine (Effexor XR)
2006	Mixed amphetamine salts (Adderall XR)
	Testosterone (Androgel)
2007	Bupropion (Wellbutrin XL)
2008	Atorvastatin (Lipitor)
	Aspirin and dipyridamole (Aggrenox)
	Esomeprazole (Nexium)
	Minocycline (Solodyn)
2009	Norethindrone and ethinyl estradiol (Loestrin)
2010	Pioglitazone (Actos)
	Pioglitazone and metformin (Actoplus met)
	Oxymorphone (Opana ER)
2012	Lidocaine (Lidoderm)
2013	Mesalamine (Asacol)

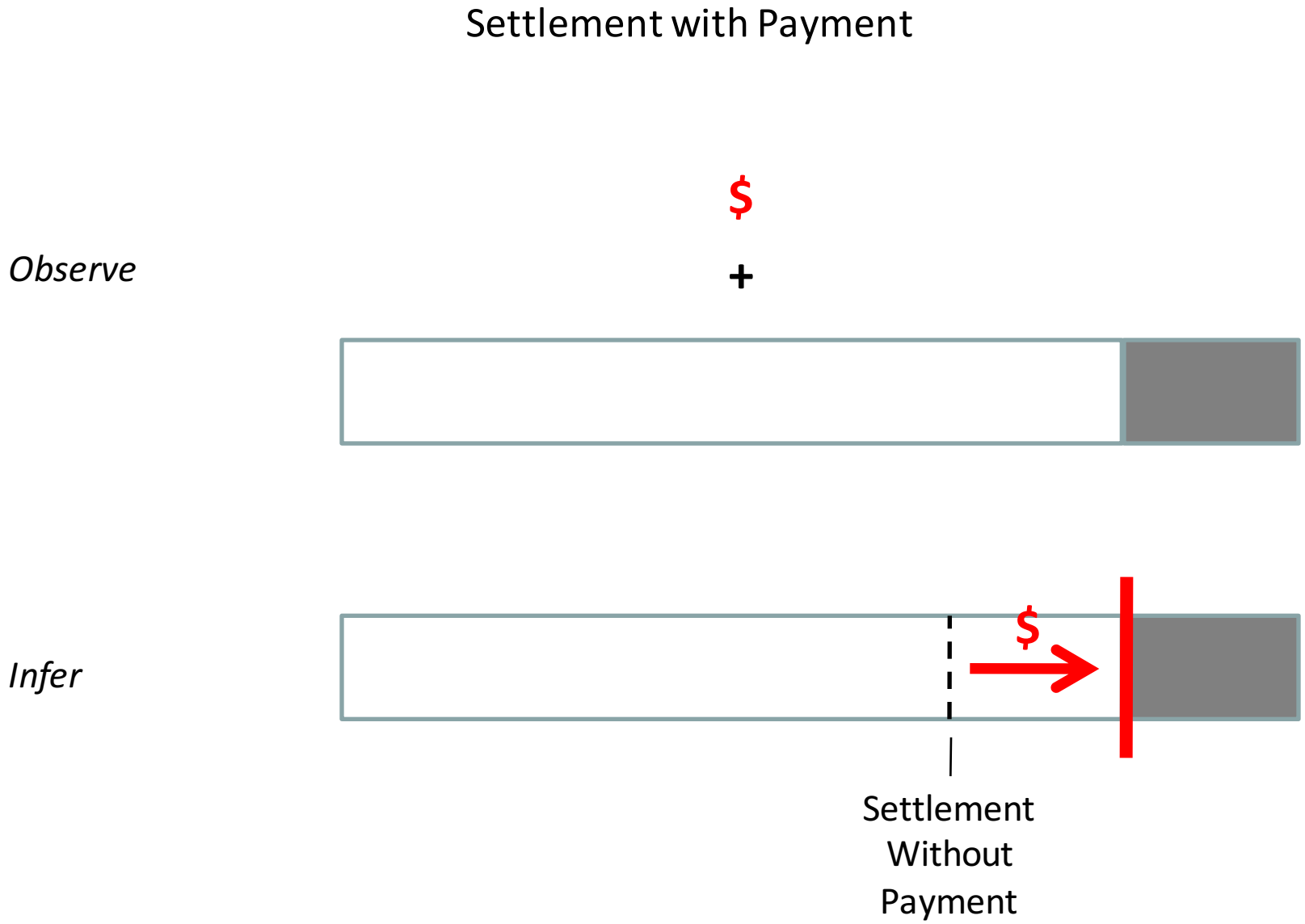
May 2015 - FTC settlement
- Injunction
- $1.2 billion in disgorgement

Note: Pending cases as of June 2015; some cases have additional claims beyond reverse payments

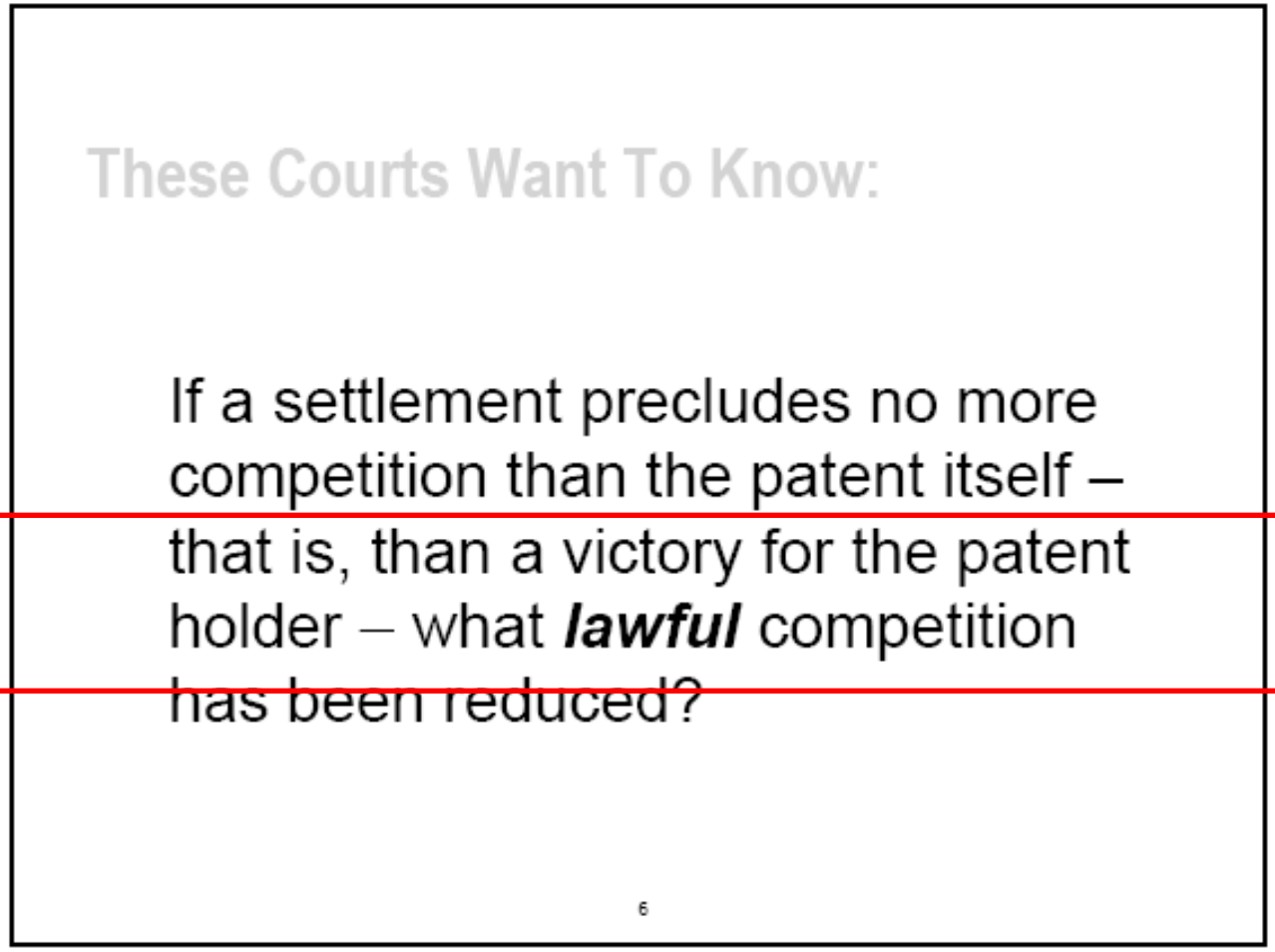
SETTLEMENT REFLECTS A COMPROMISE IN THE ENTRY DATE



THE ACTAVIS INFERENCE: INFER HARM AND DELAY FROM A LARGE PAYMENT



COURTS HAVE REJECTED THE "SCOPE OF THE PATENT" APPROACH



Source: Presentation of Kevin McDonald, Jones Day

COURTS HAVE EMBRACED THE INFERENTIAL APPROACH

[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition . . . . [T]hat consequence constitutes the relevant anticompetitive harm.

Actavis (Supreme Court 2013)

Once payment to the generic exceeds what the brand is otherwise receiving from it in products and services or would have spent to litigate, a court may fairly presume the settling parties have engaged in such conduct and should be put to the burden of coming forward with a procompetitive justification for their settlement.

Cipro (California Supreme Court 2015)

ISSUE #1: DO NO-AG AGREEMENTS COUNT?

Reverse Payment Litigation in the United States

Year of first settlement	Active ingredient (brand name)	
1997	Ciprofloxacin (Cipro)	
	Potassium chloride (K-Dur)	
2005	Metaxalone (Skelaxin)	
	Modafinil (Provigil)	
	Niacin (Niaspan)	
	Lamotrigine (Lamictal)	YES
	Venlafaxine (Effexor XR)	
2006	Mixed amphetamine salts (Adderall XR)	
	Testosterone (Androgel)	
2007	Bupropion (Wellbutrin XL)	
2008	Atorvastatin (Lipitor)	
	Aspirin and dipyridamole (Aggrenox)	
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2009	Norethindrone and ethinyl estradiol (Loestrin)	
2010	Pioglitazone (Actos)	
	Pioglitazone and metformin (Actoplus met)	
	Oxymorphone (Opana ER)	NEW FTC SUIT
2012	Lidocaine (Lidoderm)	
2013	Mesalamine (Asacol)	

Note: Pending cases as of June 2015; some cases have additional claims beyond reverse payments

ISSUE #2: CAUSATION

1. Did AstraZeneca exercise market power within the relevant market?

_____ no ~~_____~~ yes

2. Did the settlement of the AstraZeneca-Ranbaxy patent litigation include a large and unjustified payment by AstraZeneca to Ranbaxy?

_____ no ~~_____~~ yes

3. Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive, i.e. did the anticompetitive effects of that settlement outwiegh any pro-competitive justifications?

_____ no ~~_____~~ yes

4. Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?

~~_____~~ no _____ yes

5. If so, what would be the effective date of such a license?

_____, 20_____

PRODUCT SWITCHES

Conduct	Develop/acquire line extension, e.g., new dosage form, formulation, or chemical variant, or alternative therapy in same class
	Line extension has stronger or longer-lived exclusivity
	Shift patients and doctors via promotion, pricing, or withdrawal of the old product

EXAMPLE: NAMENDA

[redacted]

74. Forest's internal documents also emphasize the importance of accomplishing its product switch in advance of the entry of generic memantine. [redacted]

75. Since 2013, Defendant has undertaken an aggressive marketing campaign aimed at converting as many IR patients to XR as possible prior to Namenda IR losing exclusivity. [redacted]

[redacted] Forest ultimately became dissatisfied with the number of patients it would be able to switch through conventional strategies that relied on advocating for Namenda XR on its own merits.

Source: Amended Complaint, New York v. Actavis, PLC

EXAMPLE: NAMENDA

80. Accordingly, Forest began to consider whether it should *force* physicians and patients to switch to Namenda XR, whether they liked it or not. By at least as early as Fall 2012,

83. Defendants' internal analyses assessed the profitability of two potential scenarios, both of which in practice would result in a "forced switch." First, Forest analyzed the financial implications of a decision to discontinue Namenda IR completely. Second, Forest analyzed the

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86. According to its own predictions, the profits that Forest will make from the "forced switch" will come largely from impeding generic competition. As noted above, the typical effect of AB-rated generic entry is a 90% shift of brand market share to generics within

Source: Amended Complaint, New York v. Actavis, PLC

EXAMPLE: NAMENDA

87. During Defendant's January 21, 2014 earnings call, Forest's CEO, Brenton Saunders, unabashedly explained the motivation behind the forced switch strategy: "if we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs. They don't have the sales force, they don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again, go into to a slow decline versus a complete cliff."[12]

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[12] Forest CEO Brenton Saunders himself used the term "forced switch" in Forest's Q3 2013 Earnings Call (Jan. 21, 2014) ("We believe that by potentially doing a forced switch, we will hold on to a large share of our base users…").

Source: Amended Complaint, New York v. Actavis, PLC

PRODUCT SWITCHES

Conduct	Develop/acquire line extension, e.g., new dosage form, formulation, or chemical variant, or alternative therapy in same class
	Line extension has stronger or longer-lived exclusivity
	Shift patients and doctors via promotion, pricing, or withdrawal of the old product
Issues	New product - Is the new product better?
	Old product - Are purchasers free to choose the old product?
Responses	Product design is privileged
	No cognizable loss of competition