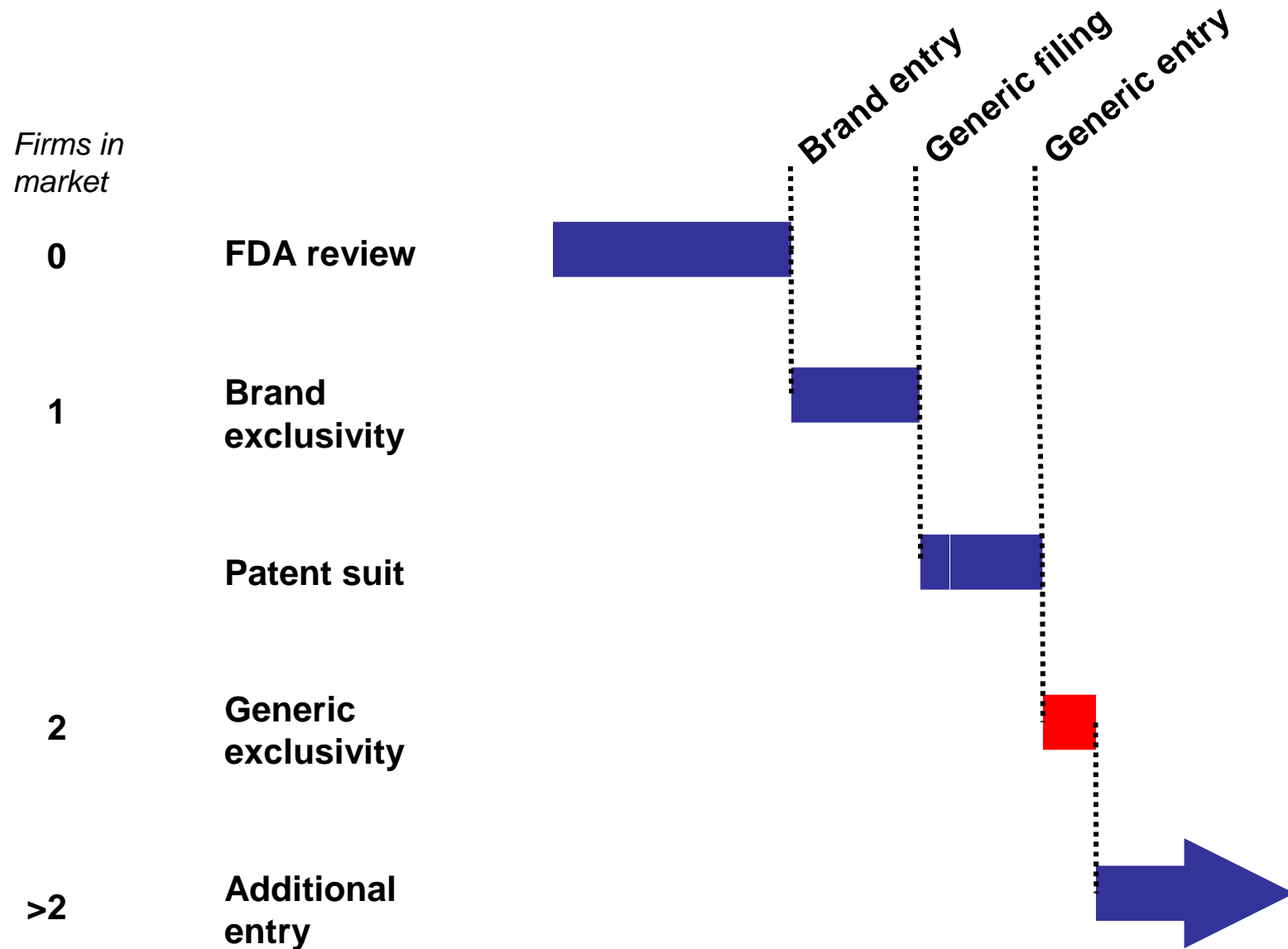


# THE HATCH-WAXMAN ACT AT 25 YEARS: MARKET FAILURE AND REFORM

Scott Hemphill  
Columbia Law School

Minnesota State Bar Association  
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# THE HATCH-WAXMAN ACT REGULATES GENERIC DRUG ENTRY

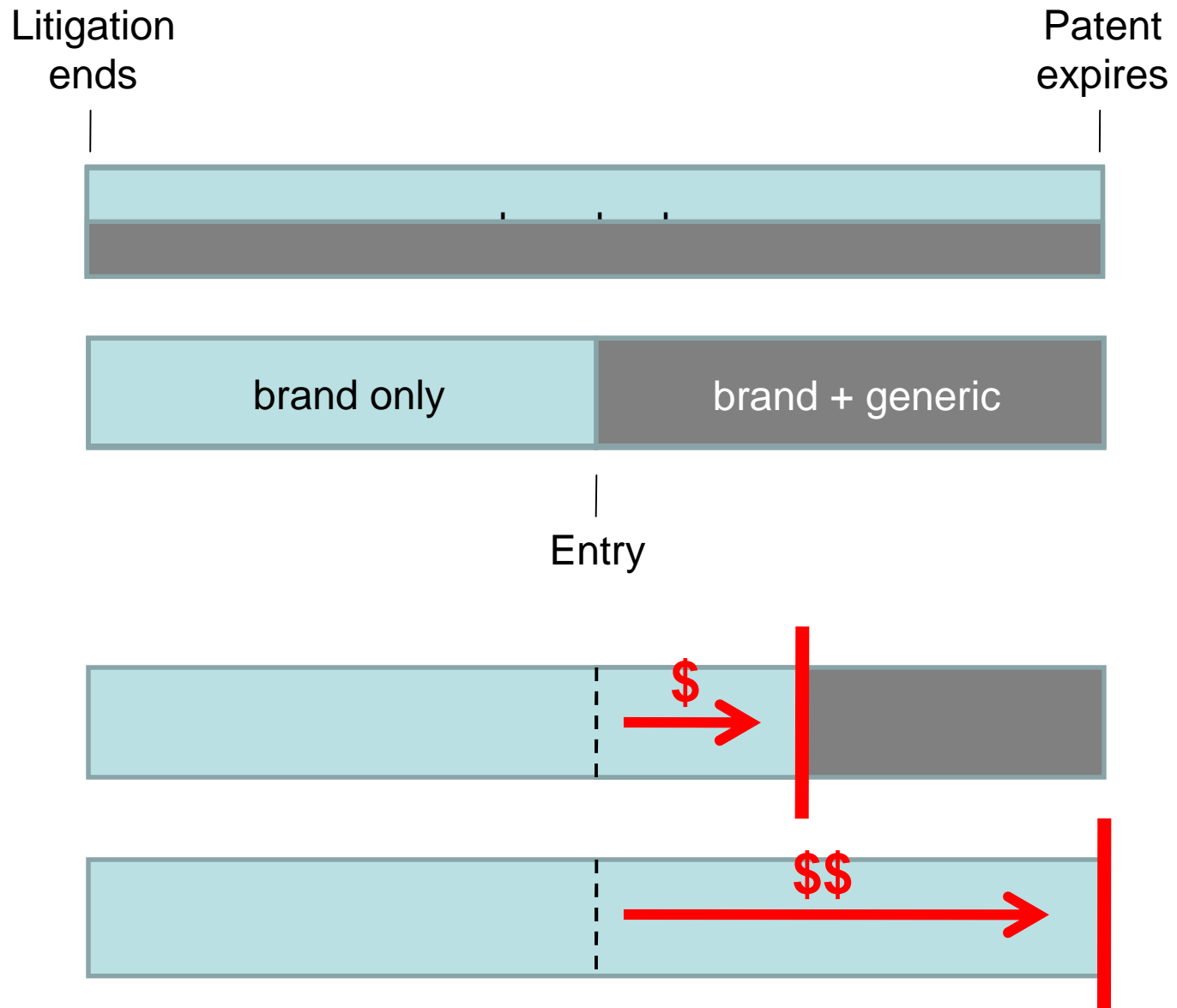


Notes: Assumes NDA approval in year 7, ANDA filing after four years of NCE exclusivity, 3 years of district court pendency, no launch at risk

# THE HATCH-WAXMAN REGIME HAS TWO UNUSUAL FEATURES

	<b>In general</b>	<b>Hatch-Waxman Act</b>
<b>Incentive to challenge patent</b>	<b>Low:</b> other challengers benefit from the win	<b>High:</b> 180-day exclusivity for <b>first</b> challenger
<b>Ability to launch at risk</b>	<b>High:</b> patentee must establish PI factors and post bond	<b>Low:</b> automatic stay blocks generic entry for more than two years

# SOME SETTLEMENTS EXCHANGE PAYMENT FOR DELAYED ENTRY



## SEVERAL COURTS HAVE DENIED ANTITRUST LIABILITY

These Courts Want To Know:

If a settlement precludes no more competition than the patent itself – that is, than a victory for the patent holder – what **lawful** competition has been reduced?

# SETTLEMENT ACTIVITY HAS INCREASED

*Columbia Law Review* (2009)

Year	Drug	Sales	Payment	Entry
1993	Nolvadex	400	Cash	9
			Authorized generic sales	
1995	BuSpar	400	Cash	5
	Zantac	2950	Cash	2
	Sinemet CR	150	Cash	11
1997	Cipro	900	Cash	7
	K-Dur*	250	Retained exclusivity	4
			Side deals (product licenses)	
1999	Naprelan	50	Retained exclusivity	3
			Side deal (intellectual property (IP))	
2005	Lamictal	1100	Generic sales (Lamictal CD)	3
	Niaspan	450	Retained exclusivity	8
			Side deals (manufacturing (mfg), promotion)	
			Generic sales (Advicor)	
	Effexor XR	2750	Retained exclusivity (+ no authorized generic)	5
			Generic sales (Effexor IR)	
2006	Provigil*	700	Retained exclusivity	6
			Side deals (IP, development, mfg, inventory)	
			Generic sales (Actiq)	
	Altace	700	Retained exclusivity	2
			Side deals (development, supply)	
	Plavix	3400	Retained exclusivity (+ no authorized generic)	5
			Side deal (inventory)	
			Deal sweeteners if settlement failed	
	Propecia	150	Retained exclusivity	7
			Generic sales (Zocor, Proscar)	
	Adderall XR*	900	Retained exclusivity (+ no authorized generic)	3
			Side deals (development, mfg, promotion)	
			Generic sales (Adderall IR)	
	AndroGel*	350	Side deals (mfg, promotion)	9
2007	Wellbutrin XL (150 mg)	850	Waived damages for 300 mg strength	1
2008	Nexium	3400	Retained exclusivity (+ no authorized generic)	6
			Side deal (manufacturing)	
			Generic sales (Prilosec and Plendil)	
	Lipitor	7200	Retained exclusivity	3
			Generic sales in Canada	
			Waived damages (Accupril)	
	Caduet	400	Joint with Lipitor	3
	Aggrenox	300	Retained exclusivity	7
			Side deal (promotion)	

# SETTLEMENTS HAVE BECOME MORE COMPLEX

*Columbia Law Review* (2009)

<b>Year</b>	<b>Drug</b>	<b>Sales</b>	
1993	Nolvadex	\$400	
1995	BuSpar	\$400	CASH
	Zantac	\$2950	
1997	Cipro	\$900	
<hr/>			
	K-Dur (2)	\$250	
2005	Effexor XR	\$2750	
2006	Provigil (4)	\$700	SIDE
	Plavix*	\$3400	DEALS
	Adderall XR (2)	\$900	
	Androgel (2)	\$350	
2008	Nexium	\$3400	

*Note:* Plavix agreement never took full effect

# SIDE DEALS PROVIDE COMPENSATION TO THE GENERIC FIRM

*Provigil—Agreements Between Cephalon and Generic Firms*

<b>Teva</b>	Patent license Purchase of active pharmaceutical ingredient
<b>Ranbaxy</b>	Patent license Purchase of active pharmaceutical ingredient
<b>Mylan</b>	Product development
<b>Barr</b>	Patent license Purchase of active pharmaceutical ingredient Settling unrelated patent litigation on favorable terms Product development

# PUBLIC ENFORCEMENT TAKES TWO FORMS

Year	Drug	Sales	
1993	Nolvadex	\$400	CA2: DOJ brief
1995	BuSpar	\$400	
	Zantac	\$2950	EDPA: FTC
1997	Cipro	\$900	
	K-Dur (2)	\$250	
2005	Effexor XR	\$2750	NDGA: FTC
2006	Provigil (4)	\$700	
	Plavix*	\$3400	
	Adderall XR (2)	\$900	
	Androgel (2)	\$350	
2008	Nexium	\$3400	

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## PUBLIC ENFORCEMENT TAKES TWO FORMS

*H.R. 3962, § 2573(b) (adding new 21 U.S.C. § 355(w)(1)(A))*

(A) **Conduct prohibited.**—It shall be unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which—

(i) an ANDA filer receives anything of value; and

(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, or sales . . . of the drug that is to be manufactured under the [relevant ANDA].

## THE PROPOSED BAN CONTAINS EXCEPTIONS

*H.R. 3962, § 2573(b) (adding new 21 U.S.C. § 355(w)(1)(B))*

(B) **Exceptions.**— . . . [S]ubparagraph (A) does not prohibit a [settlement] in which the value received by the ANDA filer includes no more than—

(i) the right to market the drug that is to be manufactured under [the relevant ANDA], before the expiration of—

(I) the patent [at issue]; or

(II) any other statutory exclusivity that would prevent the marketing of such drug; and

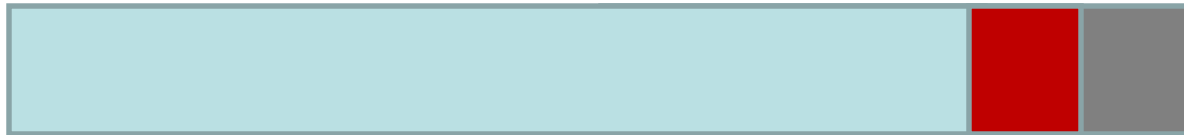
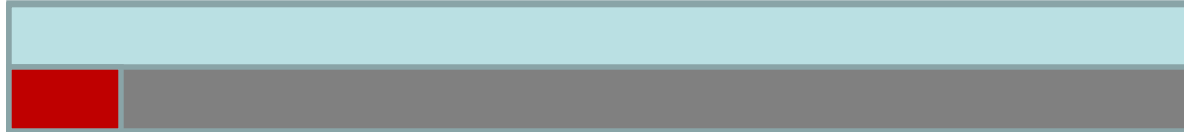
(ii) the waiver of a patent infringement claim for damages based on prior marketing of such drug.

# ARE “NO AUTHORIZED GENERIC” DEALS ILLEGAL?

<b>Year</b>	<b>Drug</b>	<b>Sales</b>	
1993	Nolvadex	\$400	
1995	BuSpar	\$400	CASH
	Zantac	\$2950	
1997	Cipro	\$900	
<hr/>			
	K-Dur (2)	\$250	
2005	Effexor XR	\$2750	
2006	Provigil (4)	\$700	SIDE DEALS
	Plavix*	\$3400	
	Adderall XR (2)	\$900	
	Androgel (2)	\$350	NO-AG
2008	Nexium	\$3400	

# IS RETAINED EXCLUSIVITY ILLEGAL?

*New York University Law Review (2006)*



## RETAINED EXCLUSIVITY IS COMMON

Year	Drug	Sales	Full?
2002	Zoloft	3000	*
2004	Femhrt	50	*
	Estrostep	50	*
2005	Lamictal CD	50	*
2006	Duoneb	250	*
	Imitrex tablets	900	
	Imitrex injection	250	
2007	Mucinex	150	*
	Diastat	100	*
	Valtrex	1350	*
	Adenoscan	350	*
	Avandia	1200	
	Avandamet	300	
	Avandaryl	100	
	Keppra	900	
	Paxil CR	350	*
	Flomax	1200	
	Cardizem LA	100	*
	Exelon	200	*
2008	Astelin	200	*
	Optivar	50	*
	Xopenex	500	*
	Miacalcin	150	*
	Depakote ER (500 mg)	700	*
	Mirapex	400	*