

AbbVie and Predecessors' Long History of Illegal Generic Delay

Brand Name	FDA Approval	Litigation	Scheme Type(s)	Drug Co.	Total Spending (2012-19)	Est. Over-Spending	FTC or DOJ Enforcement?	But-For Generic Entry	Actual (Expected) Gx Entry	Litigation Outcome or Current Status	But-For Market Assumptions
Namenda Namenda XR Namzaric	2003 2010 2014	In re Namenda Antitrust Litigation, 15-cv-07488 (S.D.N.Y.); Silbersher v. Allergan, 18-cv-03018 (N.D. Cal.)	Pay for Delay; Product Hopping; Sham Patent Listing; Fraud on the Patent Office	Forest/Allergan	\$9,454,044,086	\$7,563,235,269	No	9/22/11	7/11/15	Direct Purchasers settled for \$750 million. The Silbersher False Claims lawsuit is pending after beating Motion to Dismiss.	80% less spending 2012-19. Smaller share to next generation products.
Restasis Restasis Multidose	2002	In re Restasis Antitrust Litigation, 18-md-02819 (E.D.N.Y.)	Fraud on the Patent Office; Sham Patent Litigation; Sham Citizens Petitions	Allergan	\$6,997,357,026	\$4,470,497,129	No	5/17/14	(No Gx to Date)	Direct Purchasers settled for \$51.25 million. Indirect Purchaser class certified and pending.	80% less spending 2015-19. Smaller share to next generation product.
Humira (All)	2002	In re Humira Antitrust Litigation, 19-cv-01873 (N.D. Ill.)	Sham Patent Thicketing; Pay-for-Delay (Mkt. Allocation)	AbbVie	\$16,256,702,330	\$2,381,638,259	No	12/31/16	(6/30/2023)	District Court dismissed plaintiff's patent thicket and market allocation theories. Plaintiffs appealed and 7th Circuit decision pending.	25% less spending 2017-19. Biosimilars are less affordable.
Bystolic	2007	JM Smith Drug Corp. v. Abbvie, 20-cv-04581 (N.D. Cal.); Walgreen v. AbbVie, 20-cv-09793 (S.D. N.Y.);	Pay for Delay	Forest/Allergan	\$2,580,652,591	\$2,064,522,073	No	12/17/11	(9/17/2021)	Several class and individual purchaser actions filed in 2020 and pending.	80% less spending 2012-19.
Androgel	2000	FTC v. AbbVie, 14-cv-05151 (E.D. Pa.); King Drug Co. v. Abbott Labs, 19-cv-03565 (E.D. Pa.)	Pay for Delay; Sham Patent Litigation	AbbVie	\$1,744,393,042	\$1,268,555,349	Yes (But FTC recovery overturned.)	6/1/12	10/15/18	In FTC action, District Court ruled AbbVie used sham litigation and awarded \$448 million under 13(b). Third Circuit overturned FTC's 13(b) authority and reinstated the pay-for-delay claim. The Direct Purchaser class action is pending.	80% less spending 2013-19. Smaller share to next generation product.
Lidoderm	1999	In re Lidoderm Antitrust Litigation, 14-md-02521 (N.D. Cal.); FTC v. Allergan, 17-cv-00312 (N.D. Cal.)	Pay for Delay (Generic Side); Sham Citizens Petitions (Again)	Actavis/Allergan	\$1,872,645,537	\$850,673,641	Yes (But no monetary recovery.)	8/1/12	9/1/13	Direct Purchasers settled for \$166 million. Indirect Purchasers settled for \$104.75 million. FTC filed complaint regarding Lidoderm in 2016 and then settled that action without monetary recovery.	80% less spending 2013-15.
Niaspan	1997	In re Niaspan Antitrust Litigation, 13-md-02460 (E.D. Penn.)	Pay for Delay	AbbVie	\$836,259,407	\$643,332,604	No	4/5/09	6/26/14	Direct Purchaser class certified and pending. Indirect Purchaser class denied class cert and pending. Individual retailer cases pending.	80% less spending 2012-14.
Asacol Asacol HD Delzicol	1992 2008 2013	In re Asacol Antitrust Litigation, 15-cv-12730 (D. Mass.)	Product Hopping; Pay for Delay	Warner Chilcott/Allergan	\$825,779,393	\$545,171,760	No	7/31/13	(Limited Gx to Date)	Direct Purchasers settled for \$15 million. Indirect Purchasers class certified and then overturned on appeal by the First Circuit.	80% less spending 2014-19. Smaller share to next generation products.
Lo Loestrin Fe	2010	In re Loestrin Antitrust Litigation, 13-md-02472 (D. R.I.)	Sham Patent Litigation; Pay for Delay; Product Hopping	Actavis/Allergan	\$278,477,038	\$222,781,630	No	9/1/09	(No Gx to Date)	Indirect Purchasers settled claims for \$62.5 million. Direct Purchasers settled claims for \$120 million. Others claims from CVS and Rite Aid were settled for undisclosed amounts.	80% less spending 2012-19. Smaller share to next generation products.
Botox	1991	In Matter of Allergan and Inamed, FTC No. 061-0031 (2006); Tawfilis v. Allergan, 15-cv-00307 (S.D. Cal.);	Merger Violation; Pay for Delay (Mkt. Allocation)	Allergan	\$232,369,321	\$48,666,756	No	1/1/08	(Limited Gx to Date)	FTC required divestment of emerging Botox competitor as part of a 2005 merger. That competitor never came to market. Direct Purchasers settled Tawfillis case for \$13.45 million.	25% less spending 2012-19. Biosimilars are less affordable.
Zymar Zymaxid	2003 2010	Hartig Drug Co. v. Senju, 14-cv-00719 (D. Del.); Apotex v. Allergan, 12-cv-00196 (D. Del.)	Sham Patent Litigation; Fraud on the Patent Office; Product Hopping	Allergan	\$55,134,650	\$37,013,912	No	6/15/10	2/3/13	Direct Purchasers settled for \$9 million. Apotex reached undisclosed settlements in its competitor antitrust cases against Allergan, Kyorin, and Senju.	80% less spending 2012-13.
					\$41,133,814,422	\$20,096,088,381					

Endnotes:

[1] The Table does not include antitrust lawsuits against AbbVie before the last ten years, the ongoing massive generic price-fixing litigation that includes claims against AbbVie entities, and the National Opioid Litigation. See In re Abbott Norvir Antitrust Litigation, 562 F. Supp. 2d 1080 (N.D. Cal. 2008); In re Tricor Antitrust Litigation, 05-340 (D. Del.) (product hopping) (\$250 million settlement); In re Doryx Antitrust Litigation (Mylan v. Warner Chilcott), 12-3824 (E.D. Penn.) (product hopping); In re Generic Pharmaceuticals Pricing Antitrust Litigation, 16-md-2724 (E.D. Penn.); In re National Prescription Opiate Litigation, MDL No. 2804 (N.D. Ohio).

[2] This estimate is based on simple assumptions that generic drugs cost approximately 80% less and biosimilars cost approximately 25% less than competing brand products. The Table is intended to estimate the scale of the problem, not provide a precise damage model of every drug product. See, FDA, Generic Competition and Drug Prices (2019), available at <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>. This Table shows raw spending data and does not take into account the impact of Medicare Part D or Medicaid drug rebates.

[3] The spending data for Lo Loestrin Fe, a birth control drug, is taken from Medicaid instead of Medicare Part D.