

Appendix. Classification of Settlements with Indication of Reverse Payment

Settlement Announcement Date	Brand Drug	Brand Firm	Generic Firm	Licensed Entry Date from Settlement	Indication of Reverse Payment Classification	Possible reverse payment terms			Authorized Generic		First ANDA Generic		Second ANDA
						Agreement from Settlement (short)	Agreement from Settlement (actual)	Source	Labeler	Launch Date	Labeler	Launch Date	Launch Date
3/19/2014	Daytrana	Noven	Actavis	9/1/2015	Yes	Profit Split	"Noven will grant Actavis a non-exclusive, royalty-bearing license"	Actavis. (2014 March 19). <i>Actavis announces Daytrana® patent challenge settlement.</i> https://www.prnewswire.com/news-releases/actavis-announces-daytrana-patent-challenge-settlement-251041481.html	Padagis	6/5/2023	Mylan	6/27/2022	
4/15/2014	Generess	Warner Chilcott	Mylan	4/1/2015	No	AG Option*	"Alternatively, Mylan will be permitted to launch an authorized generic version"	Mylan. (2014 April 15). <i>Mylan announces settlement agreement for first-to-file Generess® Fe.</i> https://www.prnewswire.com/news-releases/mylan-announces-settlement-agreement-for-first-to-file-generess-fe-255320581.html	Actavis	3/15/2015	Mylan	4/1/2015	12/17/2015
4/17/2014	Celebrex	Pfizer	Teva	12/2014	Yes	Profit Split	"Under certain conditions, the license will be royalty-bearing, through the remaining term of the patent"	Reuters. (2014 April 17). <i>Teva, Pfizer settle patent lawsuit over blockbuster painkiller.</i> https://www.reuters.com/article/idUSBREA3G14N	Actavis	12/10/2014	MULTIPLE	12/10/2014	12/10/2014
5/15/2014	Gleevec	Novartis	Sun	2/1/2016	Yes	Explicit No AG	"Once Sun launched its generic Gleevec, Novartis agreed not to compete against Sun's generic Gleevec with an authorized generic"	<i>Miami-Luken, Inc. v. Novartis</i> , No. 2:18-cv-00078-TJS (E.D. Pa. Jan. 9, 2018).			Sun	2/1/2016	8/4/2016
6/2/2014	Nuvigil 100mg, 200mg	Teva	Actavis	6/1/2016	Yes				Aurobindo	8/3/2016	Actavis	6/1/2016	11/28/2016
6/20/2014	ProAir HFA	Teva	Perrigo	12/19/2016	Yes	Volume Limit	"This settlement provides a license to Perrigo and Catalent to sell limited units of Perrigo's generic version of the product for an initial period"	Teva. (2014 January 20). <i>Teva reaches settlement in ProAir® HFA patent case.</i> https://www.tevapharm.com/news-and-media/latest-news/teva-reaches-settlement-in-proair-hfa-patent-case	Teva	1/16/2019	Perrigo	2/26/2020	8/25/2020
10/10/2014	Amitiza	Sucampo	Par	1/1/2021	Yes	Profit Split; AG Option*	"Par will split with Sucampo the gross profits of the licensed products sold during the term of the agreement"	Sucampo. (2014 October 9). <i>Sucampo announces settlement agreement that resolves patent litigation in U.S. related to Amitiza.</i> https://www.sec.gov/Archives/edgar/data/1365216/000117184314004692/newsrelease.htm			Par	1/1/2021	1/3/2023
11/26/2014	Forfivo XL	IntelGenx	Wockhardt	1/15/2018	Yes	Explicit No AG; AG Option*	"Wockhardt has been granted the rights, with effect from January 15, 2018, to be the exclusive marketer and distributor of an authorized generic of Forfivo XL® in the U.S."	IntelGenx. (2014 November 26). <i>IntelGenx announces update to settlement of U.S. patent litigation related to Forfivo XL®.</i> https://www.biospace.com/intelgenx-corp-announces-update-to-settlement-of-u-s-patent-litigation-related-to-forfivo-xl	Alvogen	9/28/2018	Wockhardt	8/9/2018	
2/11/2015	Rescula	Sucampo	Par	Before July 2021	Yes	Profit Split; AG Option*	"Par will split with Sucampo the gross profits of the generic or authorized generic version sold during the term of the agreement"	Sucampo. (2015 February 11). <i>Sucampo announces resolution of Par Pharmaceutical's ANDA for Rescula®.</i> https://www.sec.gov/Archives/edgar/data/1365216/000117184315000744/newsrelease.htm					

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4/13/2015	Gralise	Depomed	Actavis	1/1/2024	No						Zydus	1/25/2024	2/26/2024
4/14/2015	Epiduo	Galderma	Actavis	Undisclosed	No				Prasco	8/3/2017	Actavis	7/27/2017	1/24/2018
4/30/2015	Banzel	Eisai	Glenmark	5/30/2022	No						Camber	5/11/2021	5/30/2021
6/3/2015	Zipsor	Depomed	Watson	3/24/2022	No				Leading	3/24/2022	Aurobindo	3/14/2022	3/24/2022
7/1/2015	Pristiq	Wyeth	Breckenridge	Undisclosed	No				Greenstone	3/1/2017	MULTIPLE	3/1/2017	3/1/2017
9/10/2015	Namenda XR	Allergan	Amneal	1/31/2020	No	AG Option*	"Amneal has an option to launch an authorized generic version of NAMENDA XR® beginning on January 31, 2021"	Allergan. (2015 September 10). <i>Allergan announces agreement with Amneal related to Namenda XR® patent litigation</i> . https://www.prnewswire.com/news-releases/allergan-announces-agreement-with-amneal-related-to-namenda-xr-patent-litigation-300140552.html	Apotex	5/9/2019	Amneal	12/22/2017	2/20/2018
10/1/2015	Remodulin	United	Sandoz	6/26/2018	Yes	Market Decline Trigger*	""Effective Launch Date' means the earliest of...v. the Market Decline Trigger Date"	Securities and Exchange Commission. (2015 September 29). <i>Settlement agreement</i> . https://www.sec.gov/Archives/edgar/data/1082554/000110465915072828/a15-17842_1ex10d2.htm			Sandoz	3/25/2019	9/30/2019
10/2/2015	Rayos	Horizon	Actavis	12/23/2022	No	Market Decline Trigger*	""Generic Entry Date' means the earliest to occur of the following dates...(y) [...***...] calendar days after the date on which Actavis provides notice that the Calculated TRX has fallen at least [...***...]"	Securities and Exchange Commission. (2015 October 01). <i>Settlement agreement</i> . https://www.sec.gov/Archives/edgar/data/1492426/000156459016013652/EX10_60.htm					
10/5/2015	Absorica	Sun/Cipher	Actavis	12/27/2020	No				Sun	5/4/2021	Actavis	4/29/2021	9/12/2023
10/5/2015	Ampyra	Acorda	Actavis	2027	No				Mylan	9/10/2018	Aurobindo	6/25/2018	7/31/2018
10/27/2015	Abstral	Orexo	Actavis	6/1/2018	No								
12/11/2015	Tamiflu	Gilead	Natco	Before 2/23/2017	Yes						Alvogen	12/12/2016	5/21/2017
12/23/2015	Revlimid	Celgene	Natco	Mar-22	Yes	Volume Limit	"Natco will receive a volume-limited license to sell generic lenalidomide in the United States commencing in March 2022. The volume limit is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry. The volume limitation is expected to increase gradually each 12 months until March of 2025"	Securities and Exchange Commission. (2022 February 9). <i>Bristol Myers Squibb Company Form 10-K</i> . https://annual-report.bms.com/assets/bms-ar/documents/bms-2021-10-K.pdf			Teva	3/3/2022	9/3/2022
5/25/2016	Folotyn	Spectrum	Teva	12/1/2022	No				Fresenius	11/15/2022			

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9/12/2022	Descovy	Gilead	Apotex (and others)	10/31/2031	No								
9/12/2022	Vemlidy	Gilead	Lupin	10/31/2031	No								
9/12/2022	Odefsey	Gilead	Apotex, Lupin, Cipla	10/31/2031	No								
2/27/2023	Ocaliva	Intercept	Apotex and MSN	Undisclosed	No								
3/3/2023	Symbicort	AstraZeneca	Mylan/Viatris	Undisclosed	No				AstraZeneca	1/3/2020	Viatris	7/31/2023	
3/29/2023	Ingrezza	Neurocrine Biosciences	Teva	2040	No								
8/30/2023	Vivitrol	Alkermes	Teva	1/15/2027	No								
10/31/2023	Yupelri	Theravance	Teva	4/23/2039	No								

* AG Option and Market Decline Trigger terms are not used to classify settlements with indication of reverse payment