

Patent Term Extension

8th Jul 2026

Apr - Jun 2026



About the Report:

As we know, while patent offers protection to innovation, patent life decides the return on R&D investments. The Hatch-Waxman Act allows drug companies to request a single extension to their patent, limited to a particular length. Consequently, drug companies continue to extend their drug monopoly through such acts of “patent life cycle management.”

To be eligible for extension, Patent Term Extensions (PTEs) need to be applied within 60 days from the date of NCE approval. Hence PTEs are filed soon after the NCE approval but many years before the first Para IV application is filed. On the other hand, a decision on PTE may take 2-4 years, coming close on the heels of the first Para IV application. In other words, a Para IV applicant needs to closely monitor the PTE as its decision can alter the return expectations of the applicant. PTE also indicates which patents innovators plan to defend the most.

The report lists the PTE petitions Filed, Accepted / Denied / Withdrawn in a given quarter. This is also integrated into our Para IV Insights database to ensure that our generic launch timelines become even more accurate.

Source of Information:

1. Regulatory documents
2. Orange Book
3. GenUS database
4. USFDA approved Drug Labels

Patent Term Extension (Apr – Jun 2026)

Patent Extension Filed

Sr. No.	Brand Name / Generic / Appl No.	Strength, Dosage	Innovator	PTE applied for and its Expiry	Extension Period (In Days) & New Expiry Date	NCE Expiry	Drug Complexity	Doc Link
1.	Cardamyst (Etripamil) 218571	70MG ; Nasal Spray	Milestone Pharms USA	9227918 (June 19, 2028)	2206, (July 04, 2034)	Dec 12, 2030	Complex Inhalers (Metered Dose Inhalers, Dry Powder Inhalers, Nasal Sprays), Drug-Device Combination	Link
2.	Cardamyst (Etripamil) 218571	70MG ; Nasal Spray	Milestone Pharms USA	9463179 (June 19, 2028)	2066, (Feb 14, 2034)	Dec 12, 2030	Complex Inhalers (Metered Dose Inhalers, Dry Powder Inhalers, Nasal Sprays), Drug-Device Combination	Link
3.	Cardamyst (Etripamil) 218571	70MG ; Nasal Spray	Milestone Pharms USA	10010522 (June 19, 2028)	1751, (Apr 5, 2033)	Dec 12, 2030	Complex Inhalers (Metered Dose Inhalers, Dry Powder Inhalers, Nasal Sprays), Drug-Device Combination	Link
4.	Cardamyst (Etripamil) 218571	70MG ; Nasal Spray	Milestone Pharms USA	10117848 (April 13, 2036)	1688, (Nov 26, 2040)	Dec 12, 2030	Complex Inhalers (Metered Dose Inhalers, Dry Powder Inhalers, Nasal Sprays), Drug-Device Combination	Link
5.	EXDENSUR (depemokimab- ulaa) BLA 761458	100 mg ; Injection	Glaxosmithkline LLC	10,787,509 May 24, 2038	572, Dec 16, 2039	NA	Biosimilar	Link

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6.	Lerochol (Lerodalcibep- LIGA) BLA 761427	300mg/1.2ml ; Injectable; Injection	LIB Therapeutics, INC.	May 16, 2039	210, Dec 12, 2039	NA	Biosimilar	Link
7.	Myqorzo (Aficamten) 219083	5mg, 10mg, 15mg, 20mg ; Tablet	Cytokinetics	10836755 Jan 18, 2039	355, Dec 19, 2039	Dec 12, 2030	NA	Link
8.	Nereus (Tradipitant) 220152	85mg Capsule	Vanda Pharmaceuticals	10,772,880 March 4, 2036	1150, Apr 28, 2039	Dec 30, 2030	NA	Link
9.	Nereus (Tradipitant) 220152	85mg Capsule	Vanda Pharmaceuticals	10,821,099 Mar 4, 2036	1126, Apr 3, 2039	Dec 30, 2030	NA	Link
10.	Nereus (Tradipitant) 220152	85mg Capsule	Vanda Pharmaceuticals	11,324,735 Mar 4, 2036	849, Jul 1, 2038	Dec 30, 2030	NA	Link
11.	Nereus (Tradipitant) 220152	85mg Capsule	Vanda Pharmaceuticals	12,318,375 Aug 9, 2036	211 Mar 8, 2037	Dec 30, 2030	NA	Link
12.	Nuzolvence (Zoliflodacin) 219491	3gm/Packet ; For Suspension	Entasis Therap	9,187,495 Jan 21, 2034	1826, Jan 21, 2039	Dec 12, 2030	NA	Link
13.	Voyxact	400MG/2ml; Injectable	Otsuka Pharm CO LTD	10,385,123	1098,	NA	Biosimilar	Link

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Sr. No.	Brand Name / Generic / Appl No.	Strength, Dosage	Innovator	PTE applied for and its Expiry	Extension Period (In Days) & New Expiry Date	NCE Expiry	Drug Complexity	Doc Link
	(Sibeprenlimab-Szsi) BLA 761434			Nov 23, 2036	Nov 25, 2039			
14.	YARTEMLEA (Narsoplimab-wuug) BLA 761152	370 mg/2 mL; Injectable	Omeros Corp	9,011,860 May 4, 2032	1,826, May 4, 2037	NA	Biosimilar	Link
15.	Adquey (Difamilast) 219474	1%; Ointment	Acrotech (Otsuka)	9,181,205 Aug 29, 2033	1826 Aug 29, 2038	Feb 12, 2031	NA	Link
16.	Adquey (Difamilast) 219474	1%; Ointment	Acrotech (Otsuka)	10,588,893 Dec 31, 2036	1138, Feb 12, 2040	Feb 12, 2031	NA	Link
17.	Adquey (Difamilast) 219474	1%; Ointment	Acrotech (Otsuka)	11,414,391 Apr 3, 2039	315, Feb 12, 2040	Feb 12, 2031	NA	Link
18.	Adquey (Difamilast) 219474	1%; Ointment	Acrotech (Otsuka)	11,840,512 Apr 3, 2039	315, Feb 12, 2040	Feb 12, 2031	NA	Link
19.	Adquey (Difamilast) 219474	1%; Ointment	Acrotech (Otsuka)	RE46792 Mar 1, 2028	1826, Mar 1, 2033	Feb 12, 2031	NA	Link

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20.	Hyrnuo (Sevabertinib) 219972	10mg ; Tablet	Bayer	10428063 Jan 25, 2036	896, Mar 24, 2038	Nov 19, 2030	NA	Link
21.	Yuviwel (Navepegritide) 219164	1.3mg/Vial, 2.8mg/Vial, 5.5mg/Vial; Powder	Ascendis	10,835,578 Jan 5, 2037	1132, Feb 11, 2040	Feb 27, 2031	Molecular weight greater than 1000 Daltons , Polymeric Compounds , Peptide Compounds	Link
22.	Yuviwel (Navepegritide) 219164	1.3mg/Vial, 2.8mg/Vial, 5.5mg/Vial; Powder	Ascendis	11,154,593 Jan 5, 2037	960, Aug 23, 2039	Feb 27, 2031	Molecular weight greater than 1000 Daltons , Polymeric Compounds , Peptide Compounds	Link
23.	Yuviwel (Navepegritide) 219164	1.3mg/Vial, 2.8mg/Vial, 5.5mg/Vial; Powder	Ascendis	11,224,661 (January 5, 2037)	916, Jul 12, 2039	Feb 27, 2031	Molecular weight greater than 1000 Daltons , Polymeric Compounds , Peptide Compounds	Link

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