

Patent Term Extension

13th Aug 2025

Jul - Sept 2025



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The report lists the PTE petitions Filed, Accepted / Denied / Withdrawn in a given quarter.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 (Jul - Sept 2025)

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.	Anzupgo (Delgocitinib) 219155	2%, Cream ; Topical	Leo Pharms (Japan Tobacco INC)	8609647 Sept 19, 2031	1827, Sept 19, 2036	Jul 23, 2030	-	Premium Content
2.	Tepadina And Sodium Chloride (Thiotepa) 208264	200mg Powder; Intravenous	Adienne Pharma	9931458 May 31, 2037	531, Nov 13, 2038	Expired	-	
3.	Ekterly (Sebetralstat) 219301	300 mg Tablets	Kalvista	11739068 Jun 23, 2037	529, Dec 04, 2038	Jul 03, 2030	-	
4.	Ekterly (Sebetralstat) 219301	300 mg Tablets	Kalvista	11234939 Jan 26, 2039	159, Jul 03, 2039	Jul 03, 2030	-	
5.	Ekterly (Sebetralstat) 219301	300 mg Tablets	Kalvista	11230537 Dec 25, 2037	556, Jul 03, 2039	Jul 03, 2030	-	
6.	Ekterly (Sebetralstat) 219301	300 mg Tablets	Kalvista	11198691 Nov 26, 2035	840, Mar 15, 2038	Jul 03, 2030	-	
7.	Ekterly (Sebetralstat)	300 mg Tablets	Kalvista	11084809	903,	Jul 03, 2030	-	

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	219301			Nov 26, 2035	May 17, 2038			Premium Content
8.	Ekterly (Sebetralstat) 219301	300 mg Tablets	Kalvista	11001578 Nov 26, 2035	949, Jul 02, 2038	Jul 03, 2030	-	
9.	Ekterly (Sebetralstat) 219301	300 mg Tablets	Kalvista	10611758 Nov 26, 2035	1148, Jan 17, 2039	Jul 03, 2030	-	
10.	Ekterly (Sebetralstat) 219301	300 mg Tablets	Kalvista	10364238 Nov 26, 2035	1263, May 12, 2039	Jul 03, 2030	-	
11.	Andembry (garadacimab-gxii) B761367	200mg/1.2ml Injectable ; Subcutaneous	CSL Behring LLC	9518127 May 04, 2033	1626, Oct 16, 2037	NA	Biosimilar	
12.	Andembry (garadacimab-gxii) B761367	200mg/1.2ml Injectable ; Subcutaneous	CSL Behring LLC	11174321 Oct 14, 2037	1014, July 24, 2040	NA	Biosimilar	
13.	Tryptyr (Acoltremon) 217370	0.003% Solution / Drops ; Ophthalmic	Alcon Labs	10028920 9433679 9095609 Sept 08, 2031	1050, July 24, 2034	May 28, 2030	-	

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14.	ENFLONSIA (Clesrovimab-cfor) B761432	105mg/0.7ml Injection ; Solution	Merck Sharp Dohme	9963500 Oct 27, 2036	955, Jun 09, 2039	NA	Biosimilar	Premium Content
15.	Qfitlia (Fitusiran) 219019	Eq 20mg base/0.2ml, Eq 50mg base/0.5ml Solution ; Subcutaneous	Genzyme Corp	9376680 Mar 15, 2033	1781, Jan 29, 2038	Mar 28, 2030	Molecular weight greater than 1000 Daltons	
16.	Qfitlia (Fitusiran) 219019	Eq 20mg base/0.2ml, Eq 50mg base/0.5ml Solution ; Subcutaneous	Genzyme Corp	9127274 Mar 22, 2033	1826, Mar 22, 2038	Mar 28, 2030	Molecular weight greater than 1000 Daltons	
17.	Ibtrozi (Taletrectinib) 219713	Eq 200mg Base Capsule	Nuvation Daiichi Sankyo	9751887 Jun 03, 2033	1535, Jun 03, 2033	Jun 11, 2030	-	
18.	Ibtrozi (Taletrectinib) 219713	Eq 200mg Base Capsule	Nuvation Daiichi Sankyo	9,187,489	1826, Jun 03, 2038	Jun 11, 2030	-	
19.	Emrellis (Elisotuzumab vedotin-tllv) B761384	20, 100 mg Vial ; Single Dose	Abbvie INC	10603389 10383948 May 17, 2037	727, May 14, 2039	NA	Biosimilar	

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20.	Blujepa (Gepotidacin) 218230	Eq 750mg Base Tablet	GlaxoSmithKline	8389524 Feb 12, 2029	1226, Feb 12, 2034	NCE *GAIN – Mar 25, 2035	-	Premium Content
21.	Avmapki Fakzynja Co-Pack (Avutometinib Capsule; Defactinib Tablet) 219616	Eq 0.8mg Base ; Eq 200mg Base Capsule ; Tablet	Verastem INC	11400090 Oct 29, 2038	181, May 08, 2039	May 08, 2030	-	
22.	Avmapki Fakzynja Co-Pack (Avutometinib; Defactinib) 219616	Eq 0.8mg Base ; Eq 200mg Base Capsule ; Tablet	Verastem INC	7928109 Aug 21, 2029	1826, Aug 21, 2034	May 08, 2030	-	
23.	Avmapki Fakzynja Co-Pack 219616	Eq 0.8mg Base ; Eq 200mg Base Capsule ; Tablet	Verastem INC	7897792 Feb 09, 2027	1826, Feb 09, 2032	May 08, 2030	-	

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24.	Imaavy (Nipocalimab-aahu) B761430	300mg/1.62ml, 1200mg/6.5ml ; Injectable ; Injection	Janssen Biotech	10676526 Jul 26, 2036	1007 Apr 29, 2039	NA	Biosimilar	

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