

Introduction

The report includes patent litigations in the forms of Para IV litigations and Biosimilar patent litigations.

The report highlights all important opportunities for the generic companies based on the latest patent litigation updates. The analyses provides an insight into each product opportunity for generic companies in terms of (1) likely timeline of the first generic launch in US (2) potential competition on the first day of launch and (3) companies likely to benefit in case of a probable launch under low competition.

The analyses get updated every time when an important development as regards the product patent litigation happens. In other words, it is not only comprehensive but also updated. We publish this report every month covering important updates on Para IV litigation

Important Para IV events are following events related to Para IV litigations:

- New Para IV applications filed
- Litigation dismissals
- Final judgments
- Patent related opinions and judgments
- PTAB updates

Sources of information:

- US Courts documents
- Company SEC filings / Annual Reports
- USFDA
- USPTO
- PTAB

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Table 1: New Litigations and Updates

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1	TROKENDI XR 25 mg, 50 mg, 100 mg Capsule ; Extended Release	TOPIRAMATE	Microlabs	Supernus has voluntarily dismissed litigation against Microlabs. We assume it to be settlement.
2	TROKENDI XR 200 mg ; Capsule Extended Release	TOPIRAMATE	<p>Premium Content</p>	
3	Neupro	Rotigotine		
4	Oxtellar XR 150, 300 mg; Tablet, Extended Release	Oxcarbazepine		
5	Oxtellar XR 600 mg; Tablet, Extended Release	Oxcarbazepine		
6	Adzenys XR- ODT	Amphetamine		
7	Xeljanz 5 mg; Tablet	Tofacitinib		
8	Xeljanz 10 mg; Tablet	Tofacitinib		
9	Tivicay	Dolutegravir Sodium		
10	Gattex Kit	Teduglutide		
11	Entresto	Sacubitril; Valsartan		
12	Dovato	Dolutegravir Sodium and		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
		Lamivudine		<p>Premium Content</p>
13	Venclexta	Venetoclax		
14	Edarbi	Azilsartan Kamedoxomil		
15	Triumeq	Abacavir Sulfate, Dolutegravir and Lamivudine		
16	Xtandi	Enzalutamide		
17	Exparel 133 mg/10 mL ; Injectable Suspension	Bupivacaine Liposome		
18	Exparel 266 mg/20 mL Injectable Suspension	Bupivacaine Liposome		
19	Emerphed	Ephedrine sulfate		
20	Erleada	Apalutamide		
21	Cinvanti	Aprepitant		
22	Edarbyclor	Azilsartan Medoxomil and Chlorthalidone		
23	Radicava ORS	Edaravone		
24	Caplyta 10.5 and 21 mg ; Capsule	Lumateperone Tosylate		
25	Caplyta 42 mg ; Capsule	Lumateperone Tosylate		

Para IV Winners and Losers December 2024

Date : 4th January 2025

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
26	Selenious Acid Eq 600mcg Selenium/10ml ; Solution, Intravenous	Selenious Acid		

Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Cresemba 186 mg ; Capsule	Isavuconazonium Sulfate		
2.	Cresemba 74.5 mg ; Capsule	Isavuconazonium Sulfate		
3.	Qdolo	Tramadol Hydrochloride		

Biosimilars : - None



Para IV Winners and Losers December 2024

Date : 4th January 2025

New Litigation and Update



Para IV Winners and Losers December 2024

Date : 4th January 2025

Trokendi XR (\$320m)- Supernus pharma vs Microlabs

Generic Name : TOPIRAMATE

Dosage : 25 mg, 50 mg, 100 mg Capsule ; Extended Release

Event : Supernus has voluntarily dismissed litigation against Microlabs. We assume it to be settlement.

Effect : Commoditized opportunity for Microlabs due to three companies have already launched their generics and other launch are expected in CY 2025.

Opportunity : Actavis and Zydus launched with Low Competition. Commoditized opportunity for rest of the Para IV filers.

Executive Summary :

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Actavis	No \ No	April 1, 2017	Settled	Approval	Launched on May 03, 2023
Zydus Cadila	Yes \ No	May 21, 2017	Settled	Approval	Launched On Jan 06, 2023
Par Pharma	No \ No	July 16, 2017	Settled	Approval	Launched on May 04, 2023
Ajanta Pharma	No \ No	Sep 26, 2023	Settled	Approval	On Feb 01, 2026
Torrent	No \ No	Jan 28, 2024	Ongoing / Partially Lost in DC	Tentative Approval	Between Nov 2027 and Apr 2028
Lupin	No \ No	Jan 30, 2024	Settled	None	Between Jan 2024 and Apr 2028
Alkem	No \ No	Nov 25, 2024	Settled	Approval	In CY 2025
Dr Reddy's	No \ No	Dec 09, 2024	Settled	Approval	In CY 2025
Ascent Pharms	No \ No	Dec 15, 2025	Settled	Tentative Approval	Between Dec 2025 and Apr 2028
Microlabs	No \ No	Feb 13, 2027	Settled	None	Between Feb 2027 and Apr 2028



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**Details of other products are part of
Premium Report**