

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	Nucynta ER	Tapentadol Hydrochloride	Teva	Janssen and Teva have settled litigation.
2	Xarelto 10,15,20 mg; Tablet	Rivaroxaban	<p>Premium Content</p>	
3	Xarelto 2.5 mg; Tablet	Rivaroxaban		
4	Xifaxan	Rifaximin		
5	Xeljanz 5 mg; Tablet	Tofacitinib		
6	Xeljanz 10 mg; Tablet	Tofacitinib		
7	Inlyta	Axitinib		
8	Viberzi	Eluxadolone		
9	Cabometyx	Cabozantinib S-Malate		
10	Qbrelis	Lisinopril		
11	Firmagon	Degarelix		
12	Edarbi	Azilsartan Kamedoxomil		
13	Minocin	Minocycline Hydrochloride		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
14	Slynd	Drospirenone	Premium Content	
15	Injectafer 750mg /15ml (50mg Iron/mL); Solution, Intravenous	Ferric Carboxymaltose		
16	Injectafer 1 g/20 mL (50mg Iron/mL) ; Solution, Intravenous	Ferric Carboxymaltose		
17	Injectafer 100mg /2mL (50mg Iron/mL) ; Solution , Intravenous	Ferric Carboxymaltose		
18	Injectafer 500mg /10ml ; Solution, Injection	Ferric Carboxymaltose		
19	Hemangeol	Propranolol Hydrochloride		
20	Delstrigo	Doravirine, Lamivudine and Tenofovir Disoproxil Fumarate		
21	Epidiolex	Cannabidiol		
22	Lynparza	Olaparib		
23	Wakix	Pitolisant Hydrochloride		
24	Brukinsa	Zanubrutinib		



Para IV Winners and Losers November 2024

Date : 5th December 2024

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
25	Xcopri	Cenobamate		

Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Winlevi	Clascoterone		Premium Content
2.	Cresemba	Isavuconazonium Sulfate		
3.	Evrysdi	Risdiplam		

Biosimilars : - None



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New Litigation and Update



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Nucynta ER (\$ 172m) - Assertio vs Teva

Generic Name : Tapentadol Hydrochloride

Dosage : 50,100,150,200,250 mg; Tablet, Extended Release

Event : Janssen and Teva have settled litigation.

Effect : Low competition opportunity for Teva.

Opportunity : Low competition opportunity for Para IV filers.

Executive Summary :

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Alkem	Yes \ No	Jun 23, 2016	Lost in DC	Tentative Approval	On Sep 22, 2028
Roxane	Yes \ No	Dec 19, 2016	Partially Won	Tentative Approval	On Jun 27, 2025
Actavis	No \ No	Mar 11, 2018	Partially Won	Tentative Approval	On Jun 27, 2025
Teva	No \ No	Sept 28, 2026	Settled	None	Between Sept 2026 and Sept 2028

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