

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	Tradjenta	Linagliptin	Biocon	Boehringer sued Biocon.
2	Rytary 23.75/95mg, 36.25/145mg, 48.75/195mg; Capsule, Extended Release	Carbidopa and Levodopa	Premium Content	
3	Rytary 61.25mg/ 245mg Capsule, extended release	Carbidopa and Levodopa		
4	Xifaxan	Rifaximin		
5	Kyprolis	Carfilzomib		
6	Opsumit	MACITENTAN		
7	Xeljanz 5 mg; Tablet, Oral	Tofacitinib		
8	Xeljanz 10 mg; Tablet, Oral	Tofacitinib		
9	Xeljanz XR 11 mg, Tablet; Extended release	Tofacitinib		
10	Xeljanz XR 22 mg, Tablet; Extended release	Tofacitinib		
11	Pomalyst	Pomalidomide		

Para IV Winners and Losers October 2025

Date : 4th November 2025

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
12	Invega Sustenna	Paliperidone Palmitate	Premium Content	
13	Veletri	Epoprostenol Sodium		
14	Tivicay	Dolutegravir Sodium		
15	Jardiance	Empagliflozin		
16	Vraylar	Cariprazine Hydrochloride		
17	Abilify Maintena Kit	Aripiprazole		
18	Biktarvy	Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate		
19	Cyclophos 500 mg/2.5 mL and 1 g/5 mL ; Solution, Intravenous	Cyclophosphamide		
20	Cyclophos 2 g/10 mL; Solution, Intravenous	Cyclophosphamide		
21	Mayzent	Siponimod Fumaric Acid		
22	Radicava ORS	Edaravone		
23	Vyndamax	Tafamidis		
24	INOmax	Nitric Oxide		
25	Nubeqa	Darolutamide		
26	Mekinist	Trametinib		
27	Multrys	Cupric Sulfate, Magnesium		

Para IV Winners and Losers October 2025

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Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
		Sulfate, Selenious Acid, Zinc Sulfate	Premium Content	
28	Tralement (1mL) ; Injection	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
29	Tralement (5mL) ; Injection	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
30	Caplyta 10.5 and 21 mg ; Capsule, Oral	Lumateperone Tosylate		
31	Caplyta 42 mg ; Capsule, Oral	Lumateperone Tosylate		
32	Jakafi	Ruxolitinib Phosphate		
33	Selenious Acid Eq 600mcg Selenium/10ml ; Solution, Intravenous	Selenious Acid		
34	Selenious Acid Eq 60mcg Selenium/ml ; Solution, Intravenous	Selenious Acid		
35	Selenious Acid Eq 12mcg Selenium/2ml ; Solution, Intravenous	Selenious Acid		
36	Cresemba	Isavuconazonium Sulfate		
37	Nuplazid - Under Suitability Petition	Pimavanserin		

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Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
38	Qelbree 150 mg ; Extended- Release Capsules	Viloxazine Hydrochloride	Premium Content	
39	Qelbree 200 mg; Extended- Release Capsules	Viloxazine Hydrochloride		
40	Suflave	Polyethylene Glycol 3350, Sodium Sulfate, Potassium Chloride, Magnesium Sulfate, Sodium Chloride		
41	Lybalvi	Olanzapine; Samidorphan L- Malate		

Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Calcium Gluconate in Sodium Chloride	Calcium Gluconate	Premium Content	
2.	Kerendia	Finerenone		

Biosimilar : None

New Litigation and Updates

Para IV Winners and Losers October 2025

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Tradjenta (\$224m) - Boehringer vs Biocon

Generic Name : LINAGLIPTIN

Dosage : 5MG ; Tablet, Oral

Event : Boehringer sued Biocon.

Effect : Commoditized opportunity for Biocon.

Opportunity : Confirmed 180 days exclusivity for Aurobindo, Mylan, MSN Labs, Invagen, Accord and Teva. Commoditized opportunity for the rest.

Executive Summary :

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Aurobindo	Yes \ Yes	Feb 4, 2018	Settled	Tentative Approval	Between Nov 2025 and Nov 2027
Hec Pharma	Yes \ No	Feb 4, 2018	Settled	Approval	After 180 days exclusivity
Mylan	Yes \ Yes	Feb 4, 2018	Ongoing	Tentative Approval	Between Nov 2025 and Nov 2027
Dr Reddy's	Yes \ No	Feb 4, 2018	Settled	Tentative Approval	After 180 days exclusivity
Zydus Cadila	Yes \ No	Feb 4, 2018	Settled	Approval Discontinued	After 180 days exclusivity
Sun Pharma	Yes \ No	Feb 4, 2018	Settled	Tentative Approval	After 180 days exclusivity
MSN Labs	Yes \ Yes	Feb 4, 2018	Settled	Tentative Approval	Between Nov 2025 and Nov 2027
Solco Healthcare	Yes \ No	Feb 4, 2018	Settled	None	After 180 days exclusivity
Prinston Pharma	Yes \ No	Feb 4, 2018	Settled	Tentative Approval	After 180 days exclusivity
Cipla (Invagen)	Yes \ Yes	Feb 4, 2018	Settled	Approval	Between Nov 2025 and Nov 2027
Accord (Intas)	Yes \ Yes	Feb 4, 2018	Settled	Tentative approval	Between Nov 2025 and Nov 2027

Para IV Winners and Losers October 2025

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Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Teva	Yes \ Yes	Feb 4, 2018	Settled	Tentative approval	Between Nov 2025 and Nov 2027
HUAHAI	Yes \ No	Feb 4, 2018	Settled	None	After 180 days exclusivity
Macleods	No \ No	March 20, 2022	Settled	Tentative Approval	After 180 days exclusivity
Hetero	No \ No	Jun 05, 2025	Settled	Tentative Approval	After 180 days exclusivity
Apotex	No \ No	-NA-	Partially won in DC \ Ongoing	Tentative Approval	After 180-days exclusivity
Granules India	No \ No	Nov 13, 2026	Settled	None	After 180-days exclusivity
Biocon	No \ No	Sept 18, 2027	Settled	None	After 180-days exclusivity

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