

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

CONTENTS

Table 1: New Litigations and Updates

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1	Complera	Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Disoproxil Fumarate	Laurus	Janssen and Laurus have settled litigation over infringement of patent no. '102.
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	Opsumit	MACITENTAN		
6	Pomalyst	Pomalidomide		
7	Jardiance	Empagliflozin		
8	Bridion	Sugammadex Sodium		
9	Firdapse	Amifampridine Phosphate		

Para IV Winners and Losers August 2025

Date : 5th September 2025

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
10	Ibrance	Palbociclib	Premium Content	
11	Xywav	Calcium Oxybate, Magnesium Oxybate, Potassium Oxybate and Sodium Oxybate		
12	Lumify (OTC)	Brimonidine Tartrate		
13	Emerphed	Ephedrine sulfate		
14	Vyzulta	Latanoprostene Bunod		
15	Tymlos	Abaloparatide		
16	Yupelri	Revefenacin		
17	Wegovy	Semaglutide		
18	Sutab	Sodium Sulfate, Magnesium Sulfate and Potassium Chloride		
19	Ephedrine Sulfate	Ephedrine Sulfate		
20	Rinvoq 15 mg; Tablet Extended Release	Upadacitinib		
21	Rinvoq 45 mg; Tablet Extended Release	Upadacitinib		
22	Rinvoq 30 mg; Tablet	Upadacitinib		

Para IV Winners and Losers August 2025

Date : 5th September 2025

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
	Extended Release		Premium Content	
23	Multrys	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
24	Tralement 0.3 mg/mL, 55 mcg/mL, 60 mcg/mL, 3 mg/mL (1 mL) ; Injection	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
25	Tralement 0.3 mg/mL, 55 mcg/mL, 60 mcg/mL, 3 mg/mL (5 mL) ; Injection	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
26	Selenious Acid	Selenious Acid		
27	Selenious Acid	Selenious Acid		
28	Orgovyx	Relugolix		

Para IV Winners and Losers August 2025

Date : 5th September 2025

Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Vitrakvi	Larotrectinib Sulfate	Premium Content	
2.	Lybalvi	Olanzapine; Samidorphan L- Malate		
3.	Neffy	Epinephrine		

Table 3: Biosimilars

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Perjeta	Pertuzumab		

New Litigations and Updates

Complera (\$74m) Janssen vs Laurus Labs

Generic Name : EMTRICITABINE; RILPIVIRINE HYDROCHLORIDE; TENOFOVIR DISOPROXIL FUMARATE

Dosage : 200MG; EQ 25MG BASE; 300MG, Tablet Oral

Event : Janssen and Laurus have settled litigation over infringement of patent no. '102.

Effect : Mylan launched under 180 days exclusivity and Low competition for Laurus Labs.

Opportunity : Mylan launched under 180 days exclusivity and Low competition for Para IV filer.

Executive Summary :

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Mylan	Yes \ Yes	Feb, 2018	Settled	Approval	Launched on May 27, 2025
Laurus Labs	No \ No	Aug 12, 2027	Ongoing / Partially Settled	None	Not before Aug 2027

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