

## 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	ProAir HFA	Albuterol Sulphate	Deva Pharma	Teva and Deva have settled litigation.
2	Xifaxan	Rifaximin	<p>Premium Content</p>	
3	Janumet XR	Sitagliptin Phosphate and Metformin Hydrochloride		
4	Xtandi	Enzalutamide		
5	Xeljanz 10 mg; Tablet	Tofacitinib		
6	Xeljanz 5 mg; Tablet	Tofacitinib		
7	Entresto	Sacubitril; Valsartan		
8	Cabometyx	Cabozantinib S- Malate		
9	Kisqali	Ribociclib Succinate		
10	Lumify (OTC)	Brimonidine Tartrate		
11	Exparel 266 mg/20 mL Injectable Suspension	Bupivacaine Liposome		
12	Exparel 133 mg/10 mL ; Injectable Suspension	Bupivacaine Liposome		
13	Erleada	Apalutamide		
14	Envarsus XR	Tacrolimus		



## Para IV Winners and Losers April 2025

Date : 7th May 2025

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
15	Orilissa	Elagolix sodium		
16	Radicava ORS	Edaravone		
17	Rinvoq 15 mg; Tablet Extended Release	Upadacitinib		
18	Rinvoq 45 mg; Tablet Extended Release	Upadacitinib		
19	Rinvoq 30 mg; Tablet Extended Release	Upadacitinib		
20	Multrys	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
21	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		
22	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		

### Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Defitelio	Defibrotide Sodium	Premium Content	
2.	Gemtesa	Vibegron		
3.	Nexplanon	Etonogestrel		
4.	Ingrezza Sprinkle	Valbenazine Tosylate		
5.	Lupkynis	Voclosporin		
6.	Cosela	Trilaciclib Dihydrochloride		
7.	Verquvo	Vericiguat		
8.	Verquvo	Vericiguat		
9.	Levothyroxine Sodium	Levothyroxine sodium		

### Table 3: Biosimilars

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Eylea	aflibercept		



## Para IV Winners and Losers April 2025

Date : 7th May 2025

---

## New Litigations and Updates



## Para IV Winners and Losers April 2025

Date : 7th May 2025

### **ProAir HFA (\$1400m) - Teva vs Deva**

**Generic Name :** Albuterol Sulphate

**Dosage :** EQ 0.09MG BASE/INH; Aerosol, Metered: Inhalation

**Event :** Teva and Deva have settled litigation as court has ordered Teva to delist '712, '289, '587, '808 and '889 patents.

**Effect :** Low competition opportunity for Deva Holdings.

**Opportunity :** Low competition opportunity for all Para IV filers.

### **Executive Summary :**

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Perrigo	Yes \ No	March 5, 2015	Settled	Approval Discontinued	Launched on Feb 25, 2020
Lupin	No \ No	Sept 21, 2019	Settled	Approval	Launched on Aug 25, 2020
Amneal	No \ No	Feb 24, 2026	Ongoing	None	Not before Feb 2026
Deva Pharma	No \ No	Aug 19, 2026	Settled	None	Launch upon approval
AMPHASTAR Pharma	No \ No	-NA-	Ongoing	Approval	Launched "at risk" on Aug 06, 2024

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