

## 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	Dificid	Fidaxomicin	Sun Pharma	Merck (Cubist) settled with Sun.
2	Xeljanz 5 mg; Tablet	Tofacitinib	<div>Premium Content</div>	
3	Xeljanz 10 mg; Tablet	Tofacitinib		
4	Xeljanz XR 11 mg; Tablet, Extended Release	Tofacitinib		
5	Xeljanz XR 22 mg, Tablet; Extended release	Tofacitinib		
6	Jardiance	Empagliflozin		
7	Injectafer	Ferric Carboxymaltose		
8	Entresto	Sacubitril; Valsartan		
9	Firvanq Kit	Vancomycin Hydrochloride		
10	Trulance	Plecanatide		
11	Xarelto	Rivaroxaban		
12	Ozobax	Baclofen		
13	Biktarvy	Bictegravir Sodium,		


## Para IV Winners and Losers May 2025

Date : 6<sup>th</sup> June 2025


Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
		Emtricitabine and Tenofovir Alafenamide Fumarate	Premium Content	
14	Cyclophos	Cyclophosphamide		
15	Cinvanti	Aprepitant		
16	Sodium Thiosulfate	Sodium Thiosulfate		
17	Lokelma	Sodium Zirconium Cyclosilicate		
18	Mektovi	Binimetinib		
19	Mayzent	Siponimod Fumaric Acid		
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		
23	Jakafi	Ruxolitinib Phosphate		
24	Nexletol	Bempedoic Acid		
25	Promacta 50 mg and 75 mg ;	Eltrombopag Olamine		

## Para IV Winners and Losers May 2025

Date : 6<sup>th</sup> June 2025

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
	Tablets			
26	Promacta 12.5 mg and 25 mg ; Tablets	Eltrombopag Olamine		
27	Selenious Acid Eq 600mcg Selenium/10ml ; Solution, Intravenous	Selenious Acid		
28	Selenious Acid Eq 60mcg Selenium/ml ; Solution, Intravenous	Selenious Acid		
29	Selenious Acid Eq 12mcg Selenium/2ml ; Solution, Intravenous	Selenious Acid		
30	Lupkynis	Voclosporin		

**Table 2: First Time Para IV Filings**

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Cosela	Trilaciclib Dihydrochloride		
2.	Zonisade	Zonisamide		
3.	Fotivda	Tivozanib Hydrochloride		

**Biosimilars : None**

## New Litigations and Updates

### **Dificid (\$263m) - Actavis vs. Sun Pharma**

**Generic Name :** FIDAXOMICIN

**Dosage :** 200 mg; Tablet, Oral

**Event :** Merck (Cubist) settled with Sun on unknown terms.

**Effect :** Low competition opportunity for Sun Pharma.

**Opportunity :** Likely 180 day exclusivity for Actavis and Low competition opportunity for all para IV filer.

### **Executive Summary :**

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Actavis	Yes \ Uncertain	March 1, 2018	Settled	Approval	Between Jan 2024 (Basic patent) and Jan 2028
Sun Pharma	No \ No	Jul 13, 2027	Settled	None	Between Jul 2027 and Jan 2028

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