

## 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	Silenor	Doxepin Hydrochloride	Taro pharma	Currax and Taro have settled litigation.
2	Tasigna 150mg, 200mg Capsule	NILOTINIB HYDROCHLORIDE MONOHYDRATE	Premium Content	
3	Tasigna 50 mg; Capsule	NILOTINIB HYDROCHLORIDE MONOHYDRATE		
4	Rytary 23.75/95mg, 36.25/145mg, 48.75/195mg; Capsule, extended release	Carbidopa and Levodopa		
5	Rytary 61.25mg/ 245mg Capsule, extended release	Carbidopa and Levodopa		
6	Xifaxan	Rifaximin		
7	Xeljanz 5 mg; Tablet	Tofacitinib		
8	Xeljanz 10 mg; Tablet	Tofacitinib		
9	Gattex Kit	Teduglutide		
10	Entresto	Sacubitril; Valsartan		
11	Invega Trinza 546 mg/1.75 mL; Extended-release Injectable Suspension	Paliperidone Palmitate		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
12	Invega Trinza 819 mg/2.625 mL, Extended-release Injectable Suspension	Paliperidone Palmitate	Premium Content	
13	Invega Trinza 273 mg/0.875 mL and 410 mg/1.315 mL Extended release	Paliperidone Palmitate		
14	Ofev	Nintedanib		
15	Xarelto	Rivaroxaban		
16	Kisqali Femara Co-Pack	Ribociclib Succinate and Letrozole (Copackaged)		
17	Jynarque	Tolvaptan		
18	Kisqali	Ribociclib Succinate		
19	Nayzilam	Midazolam		
20	Cyclophos 500 mg/2.5 mL and 1 g/5 mL ; Solution, Intravenous	Cyclophosphamide		
21	Cyclophos 2 g/10 mL; Solution, Intravenous	Cyclophosphamide		
22	Tavalisse	Fostamatinib Disodium		
23	Simbrinza	Brinzolamide and Brimonidine Tartrate		
24	Wegovy	Semaglutide		

## Para IV Winners and Losers March 2025

Date : 4<sup>th</sup> April 2025

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
25	INOmax	Nitric Oxide	Premium Content	
26	Sunosi	Solriamfetol Hydrochloride		
27	Opzelura	Ruxolitinib Phosphate		
28	Wakix	Pitolisant Hydrochloride		
29	Norepinephrine Bitartrate in 0.9 % Sodium Chloride	Norepinephrine Bitartrate in 0.9 % Sodium Chloride		
30	Aponvie	Aprepitant		
31	Reyvow	Lasmiditan Succinate		
32	Jakafi	Ruxolitinib Phosphate		
33	Zepzelca	Lurbinectedin		

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

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Orladeyo	Berotrastat Hydrochloride	Premium Content	
2.	Myfembree	Estradiol, Norethindrone Acetate and Relugolix		
3.	Norepinephrine Bitartrate in 0.9% Sodium Chloride	Norepinephrine Bitartrate in 0.9% Sodium Chloride		
4.	Ryzumvi	Phentolamine Mesylate		

## Para IV Winners and Losers March 2025

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Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
5.	Orgovyx	Relugolix	Premium Content	
6.	Klisyri	Tirbanibulin		
7.	Gemtesa	Vibegron		
8.	Cabtreo	Adapalene; Benzoyl Peroxide; Clindamycin Phosphate		

**Table 3: Biosimilars**

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

## New Litigation and Update

## **Silenor (\$200m) - Currax vs Taro**

**Generic Name :** Doxepin Hydrochloride

**Dosage :** 3, 6mg ;Tablet, Oral

**Event :** Currax and Taro have settled litigation. We assume Taro can launch its generic upon approval.

**Effect :** Commoditized opportunity for Taro Pharma.

**Opportunity :** Actavis and Mylan already launched products. Commoditized opportunity for rest of the Para IV filers.

### **Executive Summary :**

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Actavis	Yes \ Yes	June 15, 2013	Settled	Approval	Launched on Jan 1, 2020
Mylan	Yes \ Yes	June 15, 2013	Settled	Approval	Launched on Jan 5, 2021
Par Pharma	No \ No	Aug 22, 2013	Settled	Approval	Launched on Sep 12, 2022
Zydus Cadila	No \ No	Dec 16, 2013	Settled	Approval	Launched on Aug 25, 2023
MSN Labs	No \ No	Feb 13, 2023	Settled	Approval	Launched on Apr 05, 2023
Aurolife Pharma	No \ No	June 30, 2024	Settled	Approval	Can launch anytime
Ajanta Pharma	No \ No	Dec 12, 2025	Settled	Approval Discontinued	Launch upon Approval
Taro pharma	No \ No	Nov 20, 2026	Settled	None	Can launch upon approval

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