

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.	Oxycontin	Oxycodone		Premium Content
2.	TROKENDI XR 25 mg, 50 mg, 100 mg Capsule ; Extended Release	TOPIRAMATE		
3.	TROKENDI XR 200 mg ; Capsule Extended Release	TOPIRAMATE		
4.	Oxtellar XR 150, 300 mg; Tablet, Extended Release	Oxcarbazepine		
5.	Oxtellar XR 600 mg; Tablet, Extended Release	Oxcarbazepine		
6.	ADRENALIN	EPINEPHRINE		
7.	Opsumit	MACITENTAN		
8.	Xeljanz XR 11 mg; Tablet, Extended Release	Tofacitinib		
9.	Xeljanz XR 22 mg, Tablet; Extended release	tofacitinib		
10.	Eliquis	Apixaban		
11.	Entresto	Sacubitril; Valsartan		
12.	Lenvima	Lenvatinib mesylate		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
13.	Venclexta	Venetoclax		Premium Content
14.	Xtandi	Enzalutamide		
15.	Jynarque	Tolvaptan		
16.	Kisqali	Ribociclib Succinate		
17.	Exparel 266 mg/20 mL Injectable Suspension	Bupivacaine Liposome		
18.	Exparel 133 mg/10 mL ; Injectable Suspension	Bupivacaine Liposome		
19.	Saxenda	Liraglutide		
20.	Emerphed	Ephedrine sulfate		
21.	Ozempic	Semaglutide		
22.	Slynd	Dropirenone		
23.	Abilify Maintena Kit	Aripiprazole		
24.	Cyclophos 500 mg/2.5 mL and 1 g/5 mL ; Solution, Intravenous	Cyclophosphamide		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
25.	Cyclophos 2 g/10 mL; Solution, Intravenous	Cyclophosphamide		Premium Content
26.	Ztlido	Lidocaine		
27.	Colazal	Balsalazide Disodium		
28.	Lokelma	Sodium Zirconium Cyclosilicate		
29.	Simbrinza	Brinzolamide and Brimonidine Tartrate		
30.	Epidiolex	Cannabidiol		
31.	Yupelri	Revefenacin		
32.	Sunosi	Solriamfetol Hydrochloride		
33.	Nexlizet	Bempeoic Acid and Ezetimibe		
34.	Selenious Acid	Selenious Acid		

Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Zepzelca	Lurbinectedin		Premium Content
2.	Stiolto Respimat	Tiotropium Bromide and Olodaterol Hydrochloride		

Biosimilar : None



Para IV Winners and Losers September 2024

Date : 2nd October 2024

New Litigation and Updates



Para IV Winners and Losers September 2024

Date : 2nd October 2024

Oxycontin (\$3000m) - Purdue Pharma vs Accord

Generic Name : Oxycodone

Dosage : 10, 15, 20, 30, 40, 60, 80 mg extended release

Event : DC has declared patent no. '908 as invalid on the ground of obviousness. Accord has won in DC.

Effect : Commoditized opportunity for Accord (Intas) due to multiple launch in CY 2025.

Opportunity : 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
Watson	Yes \ No	Sept 24, 2013	Settled	None	In CY 2025
Teva	Yes \ No	Sept 23, 2013	Won in DC and FC	None	Launch upon approval
Ranbaxy	Yes \ No	Oct 8, 2013	Settled	None	In CY 2025
Impax	Yes \ No	Oct 8, 2013	Settled	None	In CY 2025
Par Pharma	No \ No	Nov 17, 2015	Converted to Para III	None	After Aug 24, 2027
Sandoz	No \ No	Jan 7, 2014	Settled	None	In CY 2025
Amneal	No \ No	May 10, 2014	Won in DC and FC	None	Launch upon approval
Mylan	No \ No	Oct 13, 2014	Won in DC and FC	None	Launch upon approval
Abhai	No \ No	July 19, 2018	Settled	None	Between Oct 2024 and Aug 2027
Epic pharma	No \ No	Aug 17, 2018	Won in DC and FC	None	Launch upon approval
Intelli Pharma	No \ (505(b)(2)	Nov 7, 2019	Settled	None	Between Mar 2025 and Aug 2027
Ascent Pharms	No \ No	July 11, 2020	Settled	None	Between Mar 2025 and Aug 2027



Para IV Winners and Losers September 2024

Date : 2nd October 2024

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Accord (Intas)	No \ No	Feb 26, 2023	Partially Won / ongoing	None	After Aug 2027
Elite Pharma	No \ No	Mar 29, 2026	Ongoing	None	After Mar 2026

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