Para IV Winners and Losers August 2024

Date : 6th September 2024

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.	Xeljanz 5 mg; Tablet	Tofacitinib	S	
2.	Xeljanz 10 mg; Tablet	Tofacitinib		
3.	Xeljanz XR 11 mg; Tablet, Extended Release	Tofacitinib		
4.	Xeljanz XR 22 mg; Tablet, Extended Release	tofacitinib		
5.	Farxiga	Dapagliflozin		
6.	Entresto	Sacubitril; Valsartan		
7.	Dovato	Dolutegravir Sodium and Lamivudine		
8.	Firvanq Kit	Vancomycin Hydrochloride		
9.	Firdapse	Amifampridine Phosphate		
10.	Vumerity	Diroximel fumarate		
11.	Xtandi	Enzalutamide		
12.	Exparel 266 mg/20 mL Injectable Suspension	Bupivacaine Liposome	e c	

Premium Content

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Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
13.	Exparel 133 mg/10 mL ; Injectable Suspension	Bupivacaine Liposome	Premium Content	
14.	Slynd	Dropirenone		
15.	Erleada	Apalutamide		
16.	Biktarvy	Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate		
17.	Uptravi	Selexipag		
18.	Galafold	Migalastat Hydrochloride		
19.	Lynparza	Olaparib		
20.	Isentress HD	Raltegravir Potassium		

First Time Para IV Filings – None

Table 3: Biosimilars

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Eylea	aflibercept	Premium Content	
2.	Prolia and Xgeva	Denosumab		

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Xeljanz ($900m) - Pfizer vs SoecGX

Generic Name : Tofacitinib

Dosage : 5 mg; Tablet, Oral

Event : Pfizer sued SpecGX.

Effect : Commoditized opportunity for SpecGX.

Opportunity : Likely 180-day exclusivity and Low competiition opportunity for FTFs. 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
Prinston Pharma	Yes \ Yes	Sept 2, 2019	Settled	Tentative Approval	On Dec 08, 2025 (Compound Patent)
Zydus Cadila	Yes \ Yes	Sept 2, 2019	Settled	Approval	On Dec 08, 2025 (Compound Patent)
Microlabs	Yes \ Yes	Aug 14, 2019	Settled	Approval	On Dec 08, 2025 (Compound Patent)
Breckenridge	No \ No	Sept 21, 2019	Settled	Tentative Approval	After 180 days exclusivity
Ajanta Pharma	No \ No	Sept 15, 2021	Settled	None	After 180 days exclusivity
Aurobindo	No \ No	July 11, 2023	Settled	None	After 180 days exclusivity
MSN Labs	No \ No	Oct 25, 2024	Dismissed in favor of Pfizer	Tentative Approval	After 180 days exclusivity
Yaopharma	No \ No	-NA-	Para III filing	Tentative Approval	After 180 days exclusivity
Apotex	No \ No	Sep 08, 2025	Dismissed in favour of Pfizer	None	After 180-days exclusivity
Teva	No \ No	-NA-	Para III filing	Tentative Approval	After 180 days exclusivity
HeiLongJiang ZBD	No \ No	-NA-	Para III filing	Tentative Approval	After 180 days exclusivity

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Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Sun Pharma	No \ No	Nov 22, 2025	Dismissed in favour of Pfizer	None	After 180-days exclusivity
Spec Gx	No \ No	Dec 08, 2025	Ongoing	None	After 180-days exclusivity

Details of other products are part of

Premium Report

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