

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	Oracea	Doxycycline	Macleods	Galderma sued Macleods.
2	Oxycontin	Oxycodone	Premium Content	
3	TRADJENTA	LINAGLIPTIN		
4	Jentaducto	Linagliptin and Metformin Hydrochloride		
5	Xifaxan	Rifaximin		
6	Xeljanz XR 11 mg; Tablet, Extended Release	Tofacitinib		
7	Xeljanz XR 22 mg, Tablet; Extended release	tofacitinib		
8	Xeljanz	Tofacitinib		
9	Eliquis	Apixaban		
10	Tyvaso	Treprostinil Sodium		
11	Cabometyx	Cabozantinib S-Malate		
12	Uptravi	Selexipag		
13	Ozempic 2 mg/1.5 mL and 4 mg/3 mL ; Solution, Subcutaneous	Semaglutide		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
14	Ozempic 8 mg/ 3 mL; Solution, Subcutaneous	Semaglutide		Premium Content
15	Ozempic 2 mg/3 mL ; Injection	Semaglutide		
16	Erleada	Apalutamide		
17	Galafold	Migalastat Hydrochloride		
18	Multrys	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
19	Tralement 1 mL ; Injection	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
20	Tralement 5 mL ; Injection	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
21	Venclexta	Venetoclax		
22	Mavenclad	Cladribine		

Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Rybelsus	Semaglutide	Premium Content	
2.	Dojolvi	Triheptanoin		
3.	Qvar Redihaler	Beclomethasone Dipropionate		

Table 3: Biosimilars

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Prolia and Xgeva	Denosumab		



Para IV Winners and Losers October 2024

Date : 30th October 2024

New Litigation and Update



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Oracea (\$104m) - Galderma vs Macleods

Generic Name : Doxycycline

Dosage : 40 mg; Capsule, Oral

Event 1 : Galderma sued Macleods.

Event 2 : Galderma and Macleods settled litigation over unknown terms.

Effect : Commoditized opportunity for Macleods.

Opportunity : Low competition for Lupin, Dr Reddys, and Alembic. Commoditized opportunity for all other Para IV filers.

Executive Summary :

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Mylan	Yes \ No	Sept, 2011	Partially Lost in DC	Tentative Approval	After Dec 2027
Lupin	No \ No	April 22, 2024	Won in DC and FC	Approval	Launched on Apr 09, 2024
Sandoz	No \ No	Aug 23, 2013	Settled after Losing in DC	None	After Dec 2027
Impax	No \ No	Nov 26, 2013	Lost in DC	None	After Dec 2027
Amneal	No \ No	May 8, 2014	Partially Lost \ Won on '532	Tentative Approval	On Dec 24, 2025
Dr Reddy's	No \ No	Nov 18, 2025	Settled	Approval	Launched on Apr 23, 2024
Sun Pharma	505(b)(2)	NA	Settled after Losing in DC	None	After Dec 2025
Apotex	No \ No	Oct 20, 2024	Settled	Approval	Between Oct 2024 and Dec 2027
Prinston Pharma	No \ No	Jan 20, 2025	Settled	None	Between Dec 2025 and Dec 2027
Alembic	No \ No	Feb 24, 2025	Settled	Approval	Launched on Jun 27, 2024
Macleods	No \ No	Feb 22, 2027	Settled	None	Between Feb 2027



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					and Dec 2027

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