

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	Eliquis	Apixaban	Azurity (Arbor)	BMS sued Azurity (505(b)(2)).
2	Invega Sustenna	Paliperidone Palmitate	<p>Premium Content</p>	
3	Jardiance	Empagliflozin		
4	Clenpiq	Citric acid; Magnesium oxide; Sodium picosulfate		
5	Cabometyx	Cabozantinib S-Malate		
6	Juluca	Dolutegravir Sodium and Rilpivirine		
7	Alecensa	Alectinib		
8	Imvexxy	Epoprostenol Sodium		
9	Uptravi	Selexipag		
10	Edarbi	Azilsartan Kamedoxomil		
11	Xtandi	Enzalutamide		
12	Jynarque	Tolvaptan		
13	Abilify Maintena Kit	Aripiprazole		
14	Vasostriect 40 units/100 mL and 60 units/100 mL ; Solution, Intravenous	Vasopressin		



Para IV Winners and Losers December 2025

Date : 5th January 2026

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
15	Vasostrict 20 units/100 mL; Solution, Intravenous	Vasopressin	Premium Content	
16	Cinvanti	Aprepitant		
17	Edarbyclor	Azilsartan Medoxomil and Chlorthalidone		
18	Mavenclad	Cladribine		
19	Sodium Thiosulfate	Sodium Thiosulfate		
20	Galafold	Migalastat Hydrochloride		
21	Yupelri	Revefenacin		
22	Mayzent	Siponimod Fumaric Acid		
23	Caplyta 10.5 and 21 mg ; Capsule	Lumateperone Tosylate		
24	Caplyta 42 mg ; Capsule	Lumateperone Tosylate		
25	Ubrelyv	Ubrogepant		
26	Calquence Tabs	Acalabrutinib Maleate		
27	Xcopri	Cenobamate		
28	Selenious Acid Eq 600mcg Selenium/10ml ; Solution, Intravenous	Selenious Acid		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
29	Selenious Acid Eq 12mcg Selenium/2ml ; Solution, Intravenous	Selenious Acid	Premium Content	
30	Cresemba 186 mg ; Capsule	Isavuconazonium Sulfate		
31	Cresemba 74.5 mg ; Capsule	Isavuconazonium Sulfate		
32	Verquvo 2.5 mg ; Tablet	Vericiguat		
33	Verquvo 5 and 10 mg ; Tablet	Vericiguat		

Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Livmarli 9.5 mg/mL ; Oral Solution	Maralixibat Chloride	Premium Content	
2.	Livmarli 19 mg/mL ; Oral Solution	Maralixibat Chloride		
3.	Qulipta	Atogepant		

Biosimilar : None



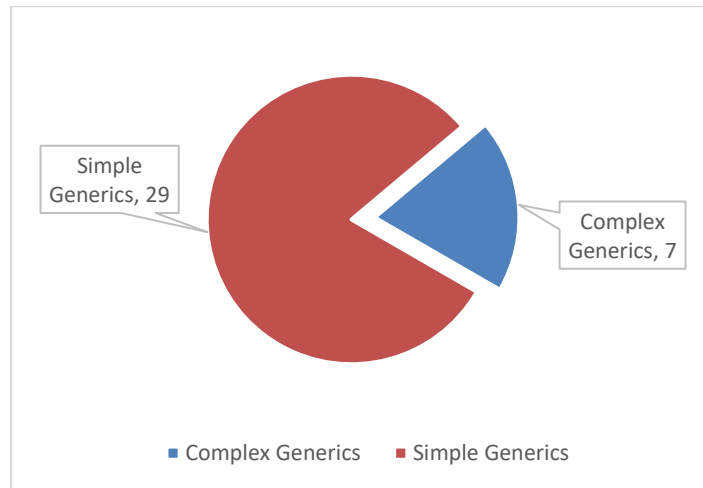
Para IV Winners and Losers December 2025

Date : 5th January 2026

Quick Insights

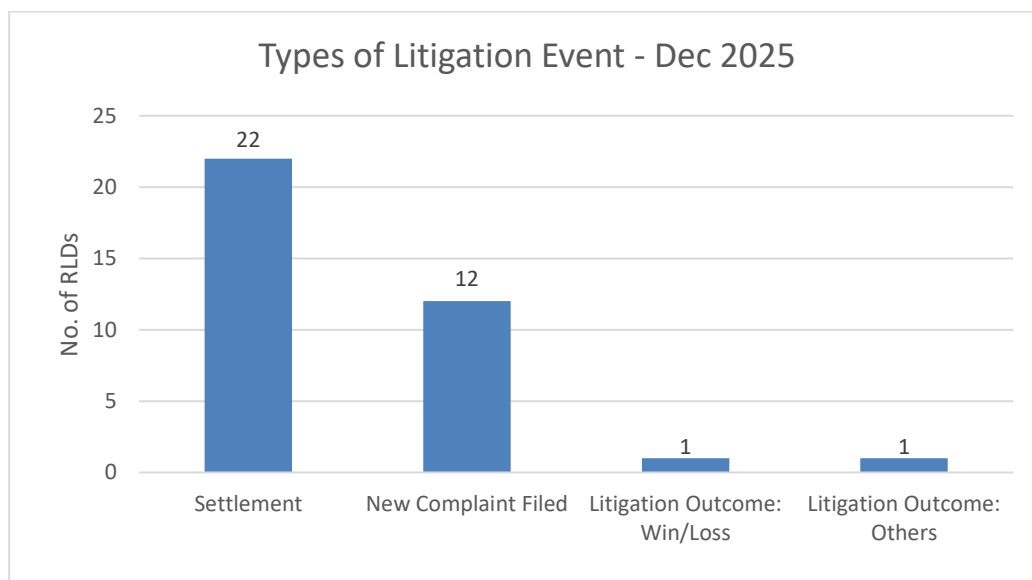
Quick Insights from Products Covered in this Report

Chart 1: Complex vs Simple Generics



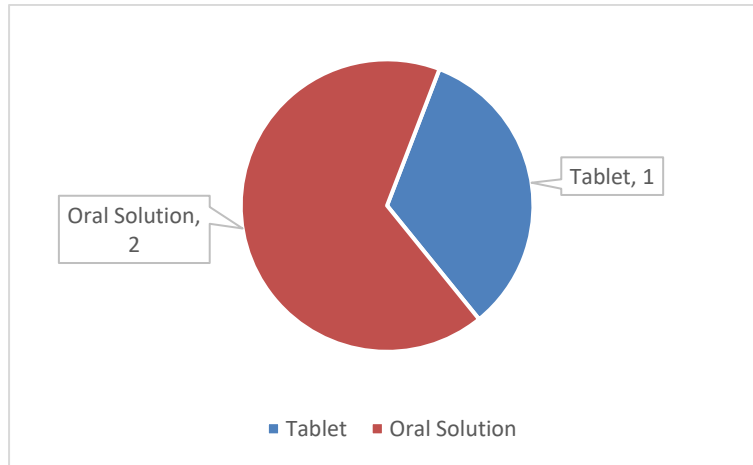
Source: Para IV Insights, Research Delta Advisors

Chart 2: Types of Litigation Events in Month of December 2025



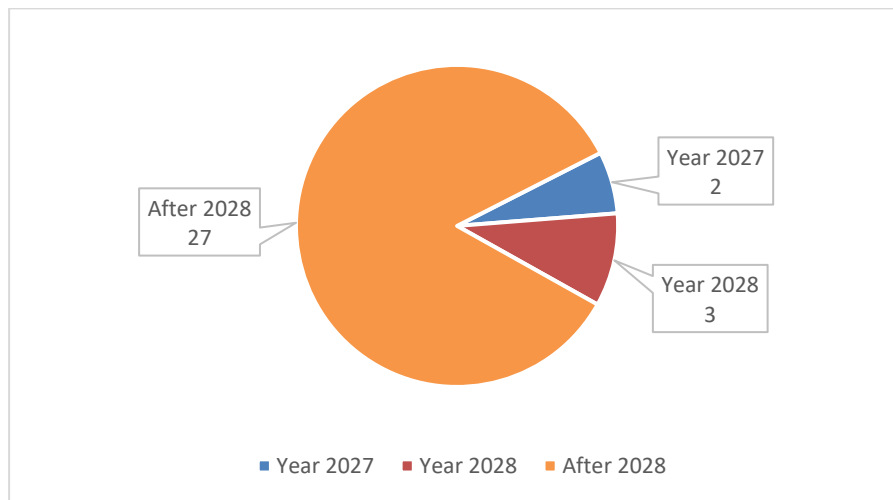
Source: Para IV Insights, Research Delta Advisors

Chart 3: Dosage based First Time Para IV Filing



Source: Para IV Insights, Research Delta Advisors

Chart 4: Upcoming Loss of Exclusivity



Source: Para IV Insights, Research Delta Advisors



Para IV Winners and Losers December 2025

Date : 5th January 2026

New Litigations and Updates



Para IV Winners and Losers December 2025

Date : 5th January 2026

Eliquis (\$4755m) - BMS vs Azurity

Generic Name : Apixaban

Dosage : 2.5, 5 mg; Tablet, Oral

Event : BMS sued Azurity (505(b)(2)) over infringement of patent no.'945*PED (Aug 24, 2031).

Effect : Commoditized opportunity for Azurity due to multiple Para IV filers.

Opportunity : Commoditized opportunity for all Para IV filers due to multiple competition.

Executive Summary :

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Aurobindo	Yes \ Yes	Oct 5, 2019	Settled	Approval Discontinued	On April 1, 2028
Mylan	Yes \ Yes	Oct 5, 2019	Settled	Approval Discontinued	On April 1, 2028
Torrent	Yes \ Yes	Oct 5, 2019	Settled	Approval	On April 1, 2028
Invagen	Yes \ No	Oct 5, 2019	Settled	None	After 180 days exclusivity
Breckenridge	Yes \ Yes	Oct 5, 2019	Settled	Approval Discontinued	On April 1, 2028
Hetero	Yes \ No	Oct 5, 2019	Settled	Approval	After 180 days exclusivity
Unichem	Yes \ No	Oct 5, 2019	Lost in DC	Tentative Approval	On Aug 24, 2031
Sunshine pharma	Yes \ No	Oct 5, 2019	Lost in DC	Tentative Approval	On Aug 24, 2031
Lupin	Yes \ Yes	Oct 5, 2019	Settled	Tentative Approval	On April 1, 2028
SigmaPharma	Yes \ No	Oct 10, 2019	Lost in DC	Tentative Approval	On Aug 24, 2031
Zydus Cadila	Yes \ No	Oct 10, 2019	Settled	Approval Discontinued	After 180 days exclusivity
Microlabs	Yes \ Yes	Oct 10, 2019	Settled	Approval Discontinued	On April 1, 2028
Accord (Intas)	Yes \ No	Oct 10, 2019	Settled	Approval	After 180 days



Para IV Winners and Losers December 2025

Date : 5th January 2026

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
					exclusivity
Sandoz	Yes \ No	Oct 10, 2019	Settled	Tentative Approval	After 180 days exclusivity
Indoco Remedies	Yes \ No	Oct 10, 2019	Settled	Approval	After 180 days exclusivity
Apotex	Yes \ No	Oct 10, 2019	Settled	Approval	After 180 days exclusivity
Bion pharma	Yes \ No	Oct 10, 2019	Settled	Approval Discontinued	After 180 days exclusivity
Teva	Yes \ No	Oct 10, 2019	Settled	Tentative Approval	After 180 days exclusivity
Sun Pharma	Yes \ Yes	Oct 10, 2019	Settled	Approval	On April 1, 2028
Emcure	Yes \ No	Oct 10, 2019	Settled	None	After 180 days exclusivity
Wockhardt	Yes \ No	Oct 10, 2019	Settled	None	After 180 days exclusivity
Dr Reddy's	Yes \ No	Oct 10, 2019	Settled	Tentative Approval	After 180 days exclusivity
Impax	Yes \ No	Oct 10, 2019	Settled	Approval Discontinued	After 180 days exclusivity
Macleods	Yes \ No	Oct 10, 2019	Settled	Approval	After 180 days exclusivity
Prinston Pharma	Yes \ No	Oct 13, 2019	Settled	Tentative Approval	After 180 days exclusivity
Biocon	No \ No	Aug 24, 2025	Settled	None	After 180-days exclusivity
Sciegen Pharma	No \ No	Sep 04, 2025	Settled	Tentative Approval	After 180-days exclusivity
Umedica	No \ No	Mar 06, 2027	Settled	None	After 180-days exclusivity



Para IV Winners and Losers December 2025

Date : 5th January 2026

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Azurity (Arbor)	No \ 505(b)(2)	May 13, 2028	Ongoing	None	Not before May 2028

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