

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	Tasigna 150mg, 200mg; Capsule	Nilotinib Hydrochloride Monohydrate	Cipla	Novartis Sued Cipla.
2	Tasigna 50 Mg; Capsule	Nilotinib Hydrochloride Monohydrate	<p>Premium Content</p>	
3	Dificid	Fidaxomicin		
4	Rytary 23.75/95mg, 36.25/145mg, 48.75/195mg ; Extended- Release Capsule,	Carbidopa And Levodopa		
5	Rytary 61.25mg/ 245mg ; Extended- Release Capsule	Carbidopa And Levodopa		
6	Myrbetriq 25 Mg; Tablet, Extended Release	Mirabegron		
7	Myrbetriq 50 Mg; Tablet, Extended Release	Mirabegron		
8	Pomalyst	Pomalidomide		
9	Injectafer 750mg /15mL (50mg Iron/mL); Solution, Intravenous	Ferric Carboxymaltose		

Sr. No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant Involved	Event
10	Injectafer 1 G/20 mL (50mg Iron/mL) ; Solution, Intravenous	Ferric Carboxymaltose	Premium Content	
11	Injectafer 100mg /2mL (50mg Iron/mL) ; Solution , Intravenous	Ferric Carboxymaltose		
12	Entresto	Sacubitril; Valsartan		
13	Lonsurf	Trifluridine; Tipiracil Hydrochloride		
14	Briviact	Brivaracetam		
15	Ofev	Nintedanib		
16	Ozobax	Baclofen		
17	Symtuza	Darunavir, Cobicistat, Emtricitabine, Tenofovir Alafenamide		
18	Giapreza	Angiotensin II Acetate		
19	Abilify Maintena Kit	Aripiprazole		
20	Vasostrict 20 Units/100 ML; Solution, Intravenous	Vasopressin		



Para IV Winners and Losers February 2025

Date : 5th March 2025

Sr. No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant Involved	Event
21	Vasostrict 40 Units/100 mL And 60 Units/100 mL ; Solution, Intravenous	Vasopressin		<p>Premium Content</p>
22	Simbrinza	Brinzolamide and Brimonidine Tartrate		
22	Epidiolex	Cannabidiol		
23	Lynparza	Olaparib		
24	Lotemax SM	Loteprednol Etabonate		
25	Wegovy	Semaglutide		
26	Xospata	Gilteritinib Fumarate		
27	Auvelity	Dextromethorphan Hydrobromide and Bupropion Hydrochloride		
28	Combivent Respimat	Albuterol Sulfate and Ipratropium Bromide		
29	Mayzent	Siponimod Fumaric Acid		
30	Spiriva Respimat	Tiotropium Bromide		
31	Genvoya	Elvitegravir, Cobicistat, Emtricitabine, Tenofovir Alafenamide		

Sr. No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant Involved	Event
32	Myoview 30 mL	Technetium TC-99M Tetrofosmin Kit	Premium Content	
33	Selenious Acid Eq 600mcg Selenium/10mL ; Solution, Intravenous	Selenious Acid		
34.	Selenious Acid Eq 60mcg Selenium/mL ; Solution, Intravenous	Selenious Acid		

Table 2: Suitability Petition - Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Nuplazid - Under Suitability Petition	Pimavanserin		

Table 3: Biosimilars : None



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New Litigation and Update



Para IV Winners and Losers February 2025

Date : 5th March 2025

Tasigna (\$859m) - Novartis vs Cipla

Generic Name : NILOTINIB HYDROCHLORIDE MONOHYDRATE

Dosage : 150mg, 200mg Capsule oral

Event : Novartis sued Cipla.

Effect : Low competition opportunity for Cipla.

Opportunity : Likely 180 days exclusivity for Apotex and Low competition opportunity for other Para IV filers.

Executive Summary :

Company	FTF Status / 180 days exclusivity	30-Months stay	Current Litigation Status	Current Approval Status	Likelihood of launch
Apotex	Yes \ Uncertain	-NA-	Not litigated	Approval Discontinued	Launch upon Approval
Teva	No \ No	Aug 20, 2026	Settled	None	Between Aug 2026 and Oct 2032
Cipla	505(b)(2) (NDA)	-NA-	Ongoing	Approval	Not before Jan 18, 2027

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