

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	Nilotinib Hydrochloride Monohydrate	Eugia pharma	Novartis has dismissed litigation against Eugia. We assume it to be settlement.
2	Tasigna	Nilotinib Hydrochloride Monohydrate		<p>Premium Content</p>
3	Xarelto	Rivaroxaban		
4	Xifaxan	Rifaximin		
5	Janumet XR	Sitagliptin Phosphate and Metformin Hydrochloride		
6	Xeljanz 5 mg; Tablet	Tofacitinib		
7	Xeljanz 10 mg; Tablet	Tofacitinib		
8	Pomalyst	Pomalidomide		
9	Invega Sustenna	Paliperidone Palmitate		
10	Jardiance	Empagliflozin		
11	Synjardy	Empagliflozin and Metformin HCL		
12	Glyxambi	Empagliflozin/Linagliptin		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
13	Clenpiq	Citric acid; Magnesium oxide; Sodium picosulfate		<p>Premium Content</p>
14	Synjardy XR	EMPAGLIFLOZIN; METFORMIN HYDROCHLORIDE		
15	Xigduo XR 5,10 mg/500mg; 5,10 mg/1000 mg, Tablet, Extended release	Dapagliflozin; Metformin hydrochloride		
16	Xigduo XR 2.5 mg/1000 mg; Tablet Extended release	Dapagliflozin; Metformin hydrochloride		
17	Entresto	Sacubitril; Valsartan		
18	Trijardy XR	Empagliflozin, Linagliptan and Metformin Hydrochloride		
19	Invega Trinza 546 mg/1.75 mL; Extended-release Injectable Suspension	Paliperidone Palmitate		
20	Invega Trinza 819 mg/2.625 mL; Extended-release Injectable Suspension	Paliperidone Palmitate		
21	Invega Trinza 273 mg/0.875 mL and 410 mg/1.315 mL Extended-release Suspension	Paliperidone Palmitate		
22	Xtandi	Enzalutamide		
23	Biktarvy	Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
24	Cyclophos 500 mg/2.5 mL and 1 g/5 mL ; Solution, Intravenous	Cyclophosphamide		<p>Premium Content</p>
25	Cyclophos 500 mg/2.5 mL and 1 g/5 mL ; Solution, Intravenous	Cyclophosphamide		
26	Cinvanti	Aprepitant		
27	Edarbyclor	Azilsartan Medoxomil and Chlorthalidone		
28	Fleqsuvy	Baclofen		
29	Mektovi	Binimetinib		
30	Xofluza	Baloxavir Marboxil		
31	Yupelri	Revefenacin		
32	Wegovy	Semaglutide		
33	Sutab	Sodium Sulfate, Magnesium Sulfate and Potassium Chloride		
34	Nubeqa	Darolutamide		
35	Mekinist	Trametinib		
36	Multrys	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
37	Tralement 0.3 mg/mL, 55 mcg/mL, 60 mcg/mL, 3 mg/mL	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
	(1 mL) ; Injection			
38	Tralement 0.3 mg/mL, 55 mcg/mL, 60 mcg/mL, 3 mg/mL (5 mL) ; Injection	Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate		
39	Jakafi	Ruxolitinib Phosphate		
40	Valtoco	Diazepam		
41	Promacta 50 mg and 75 mg ; Tablets	Eltrombopag Olamine		
42	Promacta 12.5 mg and 25 mg; Tablets	Eltrombopag Olamine		
43	Zepzelca	Lurbinectedin		
44	Cresemba 186 mg ; Capsule	Isavuconazonium Sulfate		
45	Cresemba 74.5 mg ; Capsule	Isavuconazonium Sulfate		
46	Levothyroxine Sodium	Levothyroxine sodium		
47	Qelbree 150 mg ; Extended-Release Capsules	Viloxazine Hydrochloride		
48	Qelbree 100 and 200 mg; Extended- Release Capsules	Viloxazine Hydrochloride		

Premium
Content

Table 2: First Time Para IV Filings

Sr.No.	Brand Name / Biologics Name	Generic Name / Biosimilar Name	Defendant involved	Event
1.	Eohilia	Budesonide	Premium Content	
2.	Valtoco	Diazepam		
3.	Suflave	Polyethylene Glycol 3350, Sodium Sulfate, Potassium Chloride, Magnesium Sulfate, Sodium Chloride		
4.	Immphantiv	Phenylprine Hydrochloride		
5.	Veklury	Remdesivir		

Biosimilars : None



Para IV Winners and Losers July 2025

Date : 5th August 2025

New Litigations and Updates



Para IV Winners and Losers July 2025

Date : 5th August 2025

Tasigna (\$859m) - Novartis vs Eugia (Aurobindo)

Generic Name : NILOTINIB HYDROCHLORIDE MONOHYDRATE

Dosage : 150mg, 200mg Capsule oral

Event : Novartis has dismissed litigation against Eugia. We assume it to be settlement.

Effect : Low competition opportunity for Eugia.

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 \ Yes	-NA-	Not litigated	Approval	Launched on May 26, 2025
Teva	No \ No	Aug 20, 2026	Settled	None	After 180-days exclusivity
Cipla	505(b)(2) (NDA)	-NA-	Settled	Approval	After 180-days exclusivity
Eugia pharma	No \ No	Nov 16, 2027	Settled	None	After 180-days exclusivity

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