

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 | ProAir HFA | Albuterol Sulphate | Deva Pharma | After patent being delisted. Teva and Amneal have dismissed litigation over delisted patents. |
| 2 | Tasigna 150mg, 200mg Capsule | Nilotinib Hydrochloride Monohydrate | Premium Content | |
| 3 | Tasigna 50 mg; Capsule | Nilotinib Hydrochloride Monohydrate | | |
| 4 | Xifaxan | Rifaximin | | |
| 5 | Adzenys XR- ODT | Amphetamine | | |
| 6 | Xtandi | Enzalutamide | | |
| 7 | Xeljanz XR 11mg; Tablet, Extended Release | Tofacitinib | | |
| 8 | Xeljanz XR 22mg, Tablet; Extended release | Tofacitinib | | |
| 9 | Pomalyst | Pomalidomide | | |
| 10 | Farxiga | Dapagliflozin | | |
| 11 | Inlyta | Axitinib | | |
| 12 | Entresto | Sacubitril; Valsartan | | |

Para IV Winners and Losers June 2025

Date : 7th July 2025

| Sr.No. | Brand Name / Biologics Name | Generic Name / Biosimilar Name | Defendant involved | Event |
|--------|-----------------------------------|---|--------------------------------|-------|
| 13 | Cabometyx | Cabozantinib S-Malate | <div>Premium Content</div> | |
| 14 | Lenvima | Lenvatinib mesylate | | |
| 15 | Nuplazid | Pimavanserin | | |
| 16 | Ibrance | Palbociclib | | |
| 17 | Xarelto | Rivaroxaban | | |
| 18 | Vyzulta | Latanoprostene Bunod | | |
| 19 | Mektovi | Binimetinib | | |
| 20 | Orilissa | Elagolix sodium | | |
| 21 | Galafold | Migalastat Hydrochloride | | |
| 22 | Yupelri | Revefenacin | | |
| 23 | Sutab | Sodium Sulfate, Magnesium Sulfate and Potassium Chloride | | |
| 24 | Sunosi | Solriamfetol Hydrochloride | | |
| 25 | Wakix | Pitolisant Hydrochloride | | |
| 26 | Multrys | Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate | | |

Para IV Winners and Losers June 2025

Date : 7th July 2025

| Sr.No. | Brand Name / Biologics Name | Generic Name / Biosimilar Name | Defendant involved | Event |
|--------|---|---|--------------------|-------|
| 27 | Tralement 0.3mg/mL, 55 mcg/mL, 60 mcg/mL, 3 mg/mL (1 mL) ; Injection | Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate | Premium Content | |
| 28 | Tralement 0.3mg/mL, 55 mcg/mL, 60 mcg/mL, 3 mg/mL (5 mL) ; Injection | Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate | | |
| 29 | Nexletol | Bempedoic Acid | | |
| 30 | Promacta 50mg and 75mg ; Tablets | Eltrombopag Olamine | | |
| 31 | Promacta 12.5mg and 25mg ; Tablets | Eltrombopag Olamine | | |
| 32 | Erleada | Apalutamide | | |
| 33 | Fotivda | Tivozanib Hydrochloride | | |

Table 2: First Time Para IV Filings

| Sr.No. | Brand Name / Biologics Name | Generic Name / Biosimilar Name | Defendant involved | Event |
|--------|--|-----------------------------------|-----------------------|-------|
| 1. | Erivedge | Vismodegib | Premium Content | |
| 2. | Opvee | Nalmefene Hydrochloride | | |
| 3. | Qelbree 150 mg ; Extended- Release Capsules | Viloxazine Hydrochloride | | |

Para IV Winners and Losers June 2025

Date : 7th July 2025

| Sr.No. | Brand Name / Biologics Name | Generic Name / Biosimilar Name | Defendant involved | Event |
|--------|--|-----------------------------------|-----------------------|-------|
| 4. | Qelbree 100 and 200 mg; Extended- Release Capsules | Viloxazine Hydrochloride | Premium Content | |

Table 3: Biosimilars

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

New Litigations and Updates

ProAir HFA (\$1400m) - Teva vs Deva

Generic Name : Albuterol Sulphate

Dosage : EQ 0.09MG BASE/INH; Aerosol, Metered: Inhalation

Event : After patent being delisted. Teva and Amneal have dismissed litigation over delisted patents.

Effect : Low competition opportunity for Amneal.

Opportunity : Low competition opportunity for all Para IV filers.

Executive Summary :

| Company | FTF Status / 180 days exclusivity | 30-Months stay | Current Litigation Status | Current Approval Status | Likelihood of launch |
|------------------|-----------------------------------|----------------|-----------------------------|-------------------------|------------------------------------|
| Perrigo | Yes \ No | March 5, 2015 | Settled | Approval Discontinued | Launched on Feb 25, 2020 |
| Lupin | No \ No | Sept 21, 2019 | Settled | Approval | Launched on Aug 25, 2020 |
| Amneal | No \ No | Feb 24, 2026 | Dismissed (Patent Delisted) | None | Can launch upon approval |
| Deva Pharma | No \ No | Aug 19, 2026 | Settled | None | Can launch upon approval |
| AMPHASTAR Pharma | No \ No | -NA- | Ongoing | Approval | Launched "at risk" on Aug 06, 2024 |

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