



Hatch-Waxman Lawsuits: How Often Indian Generic Makers Are Sued, FY2018–FY2025

Original analysis of 2,229 records from the Federal Judicial Center, FY2018–FY2025 (federal fiscal years, Oct. 1–Sept. 30). Published October 23, 2026. <https://settlementinsight.com/research/hatch-waxman-lawsuits-indian-generic-makers>

In fiscal 2025, 170 of the 301 Hatch-Waxman patent suits filed in U.S. district courts (56.5%) named a company belonging to an India-based drug group as the first defendant. Indian groups accounted for more than half of these cases in 7 of the eight fiscal years since the courts began coding ANDA cases separately. Our case totals for the fiscal years we checked match the federal judiciary's published counts to within one case.

56%

FY2025 ANDA suits with an India-based first defendant

301

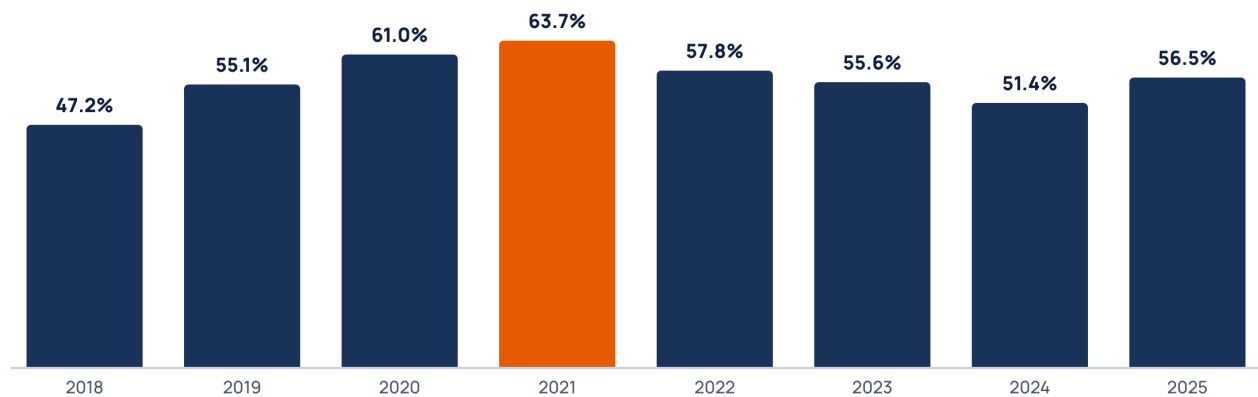
ANDA patent suits filed in fiscal 2025

24

Indian drug groups named first in FY2025 suits



Share of ANDA patent suits with an India-based first defendant



Source: Settlement Insight analysis of data from the Federal Judicial Center

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What the federal court records show

1. **A majority in fiscal 2025.** 170 of 301 ANDA patent suits (56.5%) named an entity of an India-based group as first defendant, up 5.1 percentage points from 51.4% in fiscal 2024.

2. **Above half in most years.** Across fiscal 2018 to 2025, 1,239 of 2,229 cases (55.6%) had an India-based first defendant. The highest share in the series was 63.7% in fiscal 2021.
3. **Indian groups lead the ranking.** Hetero (21 cases), Sun Pharma (17) and MSN (16) were the drug groups most often named as first defendant in fiscal 2025, counting subsidiaries and affiliates with their group; 8 of the ten most frequently named groups are headquartered in India.
4. **U.S. firms a distant second.** Groups based in the United States were first defendant in 46 fiscal 2025 cases (15.3%), and Chinese groups in 5.6%.
5. **Two courts handle nearly all cases.** 96.0% of fiscal 2025 ANDA suits were filed in the District of New Jersey or the District of Delaware.

How we measured

Data come from the Integrated Database of the Federal Judicial Center, which compiles case filings that the U.S. district courts report to the Administrative Office of the U.S. Courts. We used the civil file as held in our database on October 10, 2026, and downloaded the judiciary's Table C-2 for comparison on October 23, 2026.

We counted civil cases with nature of suit code 835 (Patent - Abbreviated New Drug Application) filed from October 1, 2017, through September 30, 2025, fiscal 2018 to fiscal 2025. The code took effect on June 1, 2017, so fiscal 2017 is incomplete and left out. A case that was closed, reopened and closed again appears twice in the database; we kept one record per district, docket number and filing date, which removed 12 duplicate records.

Each case's first-listed defendant was assigned to a corporate group and to the country where the group's ultimate parent is headquartered. A case counts as India-based when that country is India (Ultimate parent headquartered in India). U.S.-registered firms whose ownership we could not verify were counted under the United States. The full name-to-group table is in the CSV.

Our case totals match Table C-2 of the federal judiciary: 301 cases in fiscal 2025, 282 in fiscal 2024 and 337 in fiscal 2018, exactly as published, and 223 in fiscal 2021, within 0.45% of the published figure.

Checked against published figures

- NOS 835 (Patent-ANDA) civil cases commenced in U.S. district courts, 12 months ending Sept. 30, 2025: published 301, our count 301 (exact match). [Table C-2. U.S. District Courts - Civil Cases Commenced, by Basis of Jurisdiction and Nature of Suit \(September 30, 2025\)](#)
- NOS 835 civil cases commenced, 12 months ending Sept. 30, 2024 (prior-year column of the same table): published 282, our count 282 (exact match). [Table C-2. U.S. District Courts - Civil Cases Commenced, by Basis of Jurisdiction and Nature of Suit \(September 30, 2025\)](#)
- NOS 835 civil cases commenced, 12 months ending Sept. 30, 2021: published 222, our count 223 (0.45% apart). [Table C-2. U.S. District Courts - Civil Cases Commenced, by Basis of Jurisdiction and Nature of Suit \(September 30, 2021\)](#)
- NOS 835 civil cases commenced, 12 months ending Sept. 30, 2018: published 337, our count 337 (exact match). [Table C-2. U.S. District Courts - Civil Cases Commenced, by Basis of Jurisdiction and Nature of Suit \(September 30, 2018\)](#)

Limitations

- The database keeps only the first-listed defendant. Many ANDA suits name several generic companies, and cases where an Indian company is a co-defendant but not listed first are not counted as India-based, so the figures understate how many suits involve an Indian company at all.
- A case is not the same as a patent dispute. Patent holders often sue the same generic applicant over the same drug in both New Jersey and Delaware, or file separate suits against each applicant, so case counts are higher than the number of drugs or applications in dispute. Like the judiciary's own count of cases commenced, the totals also include cases that were reopened, remanded or transferred in from another district, so a single lawsuit can be counted more than once.
- Country assignment is ours and reflects corporate ownership as we understand it. Some India-headquartered firms have foreign shareholders, some U.S.-registered firms have Indian owners or affiliates that we did not count, and Indian subsidiaries of non-Indian groups, such as Mylan Laboratories Limited of Viartis, count as not India-based. For the same reason Gland Pharma of Hyderabad, in which China's Fosun Pharma has held a controlling stake throughout the period, counts under China.
- ANDA suits filed before June 1, 2017, and any ANDA cases that courts recorded under the general patent code 830 are not included. The counts say nothing about who won: they reflect lawsuits filed, not infringement found.

Data files

- [ANDA patent suits by first-defendant corporate group, FY2018-FY2025](#) (CSV, 201 rows)
- [Hatch-Waxman \(ANDA\) patent suits by fiscal year and India-based first defendant](#) (CSV, 8 rows)
- [How each recorded first-defendant name was assigned to a corporate group](#) (CSV, 493 rows)

How to cite

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