ANDA litigants flocking to New Jersey over Delaware

Nisha Shetty 24 February 2025



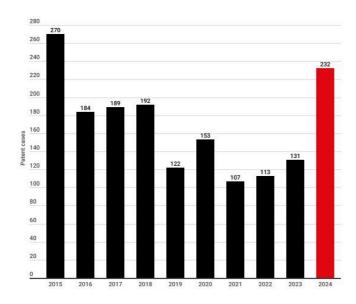
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One interesting takeaway in the <u>Docket Navigator and IAM Litigation Report Q4 2024</u> was that the US District Court for the District of New Jersey was the fifth most-popular patent venue in the country in 2024 – the highest it has been ranked since 2018.

Since the vast majority of US patent litigation targeting generic drugmakers occurs in New Jersey and Delaware, we decided to dig deeper into the development.

Using Docket Navigator data, we found that there was a surge in the number of cases filed in New Jersey in 2024, which coincided with it leapfrogging over Delaware in cases going after generic drugmakers. We explored the judicial bench strength in New Jersey – which lawyers told us is the reason for the trend – and we found that, as the number of cases began picking up in New Jersey, so too did the number of patentee wins.

Patent cases in District of New Jersey since 2015



Source: Docket Navigator

There were 232 total patent cases filed in New Jersey in 2024 – a 77% year-over-year increase. It is also the highest number of cases filed in the district since 2015. In 2016, the cases dropped by 32% and the slide continued with a low of 107 cases in 2021. The cases picked up after that but nothing quite as notable as the jump in 2024.

ANDA litigation

The majority of the patent litigation filed in New Jersey and Delaware involves Abbreviated New Drug Applications (ANDA). That is, under the Hatch-Waxman Act and the Food, Drug and Cosmetic Act, a generic drug manufacturer seeking approval from the US Food and Drug Administration to market a generic version of a patented drug may submit an ANDA.

Before submitting an ANDA, a generic drug manufacturer must study the Orange Book, a public list of each FDA-approved drug with expiration dates of patents and exclusivity. The generic drug manufacturer must then determine: which, if any, patents exist; when they expire; whether the proposed product would infringe the listed patents; or whether the listed patents may be invalid.

Using Docket Navigator data, we decided to look at where ANDA cases involving Orange Book patents were being filed over the past decade.

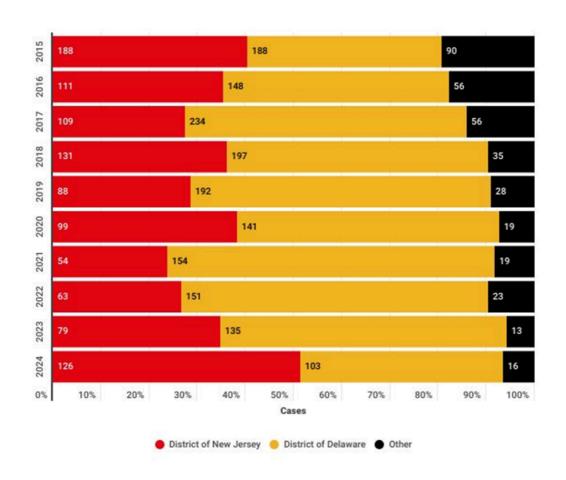
In 2015, both New Jersey and Delaware had the same number of ANDA cases: 188. Together, they two districts were responsible for 81% of the ANDA litigation in the US.

Since then, Delaware has always had more ANDA cases than New Jersey. In fact, from 2017 onwards, more than 50% of ANDA cases in the country were filed in Delaware. The biggest gap between the two districts happened in 2021 when 68% of the ANDA cases were filed in Delaware, 24% in New Jersey and the remaining 8% in other districts.

It seemed New Jersey would always come in second to Delaware in ANDA matters, but that changed in 2024.

For the first time in a decade, 51% of ANDA cases were filed in New Jersey, while 42% were filed in Delaware. New Jersey saw a 60% year-over-year increase in ANDA cases, while Delaware saw a 24% year-over-year decrease.

ANDA cases involving Orange Book patents since 2015



Source: Docket Navigator

Why cases are surging in New Jersey

The judicial bench strength is the primary reason for the uptick in cases in New Jersey, lawyers suggest.

"I believe there is a recognition on the part of both brand and generic companies and their counsel that our District of New Jersey judges have a strong working knowledge of ANDA litigation, based on their experience with such cases and those of their colleagues," says Charles Lizza, a partner at Saul Ewing responsible for its ANDA litigation practice, adding that some companies and counsel prefer to avoid certain judges in Delaware. "Both sides can expect reasonably prompt and certainly fair adjudication of their cases in the District of New Jersey."

"The fact that there are no vacancies here in the District of New Jersey is also attractive to the litigants," says Mark Makhail, an attorney at McCarter & English, explaining that in the past there were several vacancies that put pressure on the court and the litigants. "The District of New Jersey has always had a strong patent bench and with a full slate that means cases are given all the necessary attention to assure an expeditious and correct resolution."

At the moment, there are six judges (district and magistrate) in New Jersey that have seen at least 100 ANDA cases involving Orange Book patents.

Table 1: New Jersey judges with most ANDA cases since 2015

Judge	Cases	Status
Cathy L Waldor	163	Active
Lois H Goodman	163	Active
Douglas E Arpert	160	Retired in 2024
Michael A Shipp	142	Active
Tonianne J Bongiovanni	132	Active
Karen M Williams	130	Active
Stanley R Chesler	119	Active
Renee Marie Bumb	111	Active
Freda L Wolfson	99	Retired in 2023
Leda D Wettre	94	Active
Peter G Sheridan	94	Active
Brian R Martinotti	90	Active

Source: Docket Navigator

Meanwhile, Delaware has only three judges that have seen at least 100 ANDA cases involving Orange Book patents. Judge Leonard P Stark was one of Delaware's most experienced judges, but his service was terminated in 2022 when he was elevated to the US Court of Appeals for the Federal Circuit. Magistrate judges Gregory M Sleet and Sue L Robinson, who had also seen over 100 ANDA cases, retired in 2017.

Table 2: Delaware judges with most ANDA cases since 2015

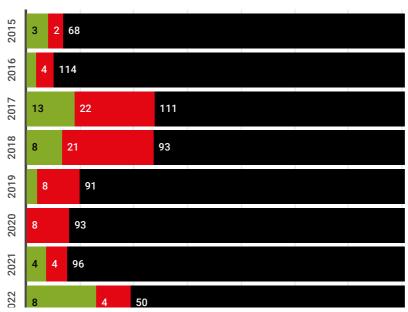
Judge	Cases	Status
Richard G Andrews	481	Active
Leonard P Stark	458	Elevated to Federal Circuit in 2022
Colm F Connolly	354	Active

Gregory M Sleet	290	Retired in 2017
Sue L Robinson	138	Retired in 2017
Maryellen Noreika	118	Active
Sherry R Fallon	90	Active
Christopher J Burke	88	Active
Mitchell S Goldberg	57	Visiting judge
Jennifer L Hall	56	Active
Gregory B Williams	55	Active
Mary Pat Thynge	35	Retired in 2023

Source: Docket Navigator

Furthermore, as cases began increasing in New Jersey and decreasing in Delaware in 2022, there were more patentee wins in New Jersey compared to Delaware from 2021 to 2023.

Outcome of terminated cases in District of New Je



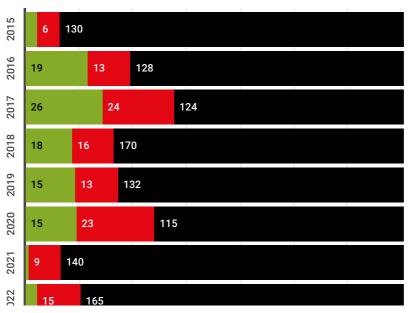
Source: Docket Navigator

In 2021, 4% of the terminated cases were patentee wins in New Jersey while in Delaware the number was 1%. Patent challengers wins in New Jersey were also 4% while in Delaware the number was 6%.

In 2022, 13% of the terminated cases were patentee wins in New Jersey while Delaware's number went up to 2%. Patent challengers wins in New Jersey were 6%, but the number was higher in Delaware (8%).

In 2023, the number of patentee wins in New Jersey rose to 21% – the highest of the decade – while only 3% of the terminated cases in Delaware had a similar result. Patent challengers wins in New Jersey slipped to 3% while the number climbed to 10% in Delaware.

Outcome of terminated cases in District of Delawa



Source: Docket Navigator

In 2024, New Jersey's patentee win rate came down to 2% while Delaware's remained at 3%. Still, the patent challenger win rate in New Jersey was a modest 3% while in Delaware it was 6%.

Nevertheless, New Jersey boasts of a more-experienced bench at the moment than Delaware so it will be interesting to see if the number of ANDA cases continues to climb in New Jersey and slip in Delaware.



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