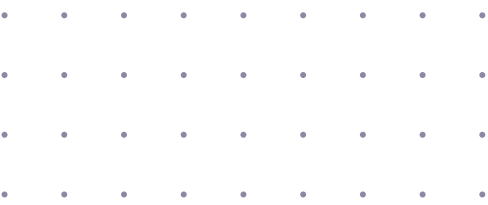**Patexia**

August 2025

ANDA Litigation 2025

Intelligence Report

July 2020 — June 2025

A comprehensive report on the **Best Performing** and **Most Active** **Hatch-Waxman Attorneys and Law Firms.**

Table of Contents.

Introduction.

The pharmaceutical landscape in the United States continues to evolve rapidly, driven in large part by challenges and opportunities surrounding generic drug competition. ANDA litigation, governed by the Hatch-Waxman Act, plays a central role in this environment, as brand-name companies defend their patents and generics challenge them through Paragraph IV certifications. Understanding trends in these disputes is essential for companies, law firms, attorneys, judges, and other stakeholders who participate in or track ANDA litigation.

In recent years, several high-revenue branded drugs, including Revlimid, Gilenya, Humira, Eliquis, and Keytruda, have faced multiple challenges including ANDA. These disputes largely reflect the commercial incentives for generic manufacturers to enter markets with substantial sales potential. The high revenue and widespread use of these medications make them particularly attractive targets, prompting both aggressive litigation and strategic settlements between brand and generic companies. This trend highlights the ongoing competitive pressure in the pharmaceutical market and underscores the importance of monitoring ANDA activity for both legal and strategic business planning.

In this report, we provide a thorough statistical overview of ANDA litigation, covering filing trends over time, the number of patents challenged per case, the most frequently cited IPC codes, case outcomes, and the typical length of cases, among others. These measures help identify both long-term patterns and recent shifts in the dynamics of Hatch-Waxman litigation. Furthermore, through a combination of publicly available data, computational analysis, and advanced scoring methodologies, we evaluate each participant's contribution to the outcomes of the cases. We assess activity levels, quantify success rates, and calculate overall performance scores, providing both granular insights into individual cases and a broader view of the ANDA litigation environment.

The goal of this report is to serve as a practical reference for decision-makers in the pharmaceutical and legal sectors, providing actionable insights based on rigorous analysis of ANDA litigation over the past five years. By combining historical data, scoring metrics, and trend analysis, we aim to equip stakeholders with the knowledge needed to understand and respond effectively to this dynamic and high-stakes segment of the pharmaceutical market.

Scope and Methodology

This report covers all ANDA litigation filed in U.S. District Courts between July 1, 2020, and June 30, 2025. Each case has been analyzed at both the proceeding and patent level, allowing us to evaluate not only overall filing activity but also the scope and frequency of patent challenges. Our coverage includes information about filing trends, courts where

cases are concentrated, patents most frequently litigated, IPC classifications, and outcome distributions.

To evaluate the activity and performance of participants, we developed computational methods and applied machine learning algorithms to isolate individual contributions

from external influences. Our methodology measures activity levels, evaluates success rates, and generates performance scores for judges, attorneys, law firms, and companies. These metrics are recalibrated across multiple dimensions to ensure fairness and comparability.

For a detailed explanation of our methodology, including ranking criteria, performance factors, and normalization techniques, refer to Section 7 of this report or visit our online methodology guide.

Who Can Use This Report and How?

ANDA litigation impacts a wide range of stakeholders, from pharmaceutical companies defending blockbuster drugs to generic manufacturers seeking market entry, as well as the attorneys and law firms representing them. Each group comes to these cases with different objectives: protecting market share, accelerating time-to-market, or building a proven litigation record.

- **Pharmaceutical companies & in-house legal/IP teams** – monitor competitor activity, understand which patents are most frequently challenged, assess risks to your portfolio, and leverage rankings and outcomes to refine litigation strategies and evaluate external counsel.
- **Law firms and attorney**s – benchmark performance against peers, track filing trends, and identify opportunities to expand practice areas. This insight also helps firms understand where work is con-

centrated and how to strategically position themselves in the ANDA litigation market.
- **Recruiters and business development professionals** - use the analysis of lateral moves and hiring patterns to improve talent acquisition, discover potential collaborations, and highlight capabilities to current or prospective clients.
- **Investors and consultants** – follow filing trends, case outcomes, and durations to better assess market dynamics and forecast future opportunities. The insights can inform portfolio strategy, risk management, and advisory recommendations in the pharmaceutical sector.

Whether you are measuring your own performance, analyzing competitors, or preparing for upcoming challenges, this report equips you with the data and insights needed to stay ahead in the competitive ANDA litigation area.

Report Contents

This edition of Patexia's ANDA Litigation Intelligence Report provides a comprehensive, five-year analysis of ANDA cases filed between **July 1, 2020, and June 30, 2025**. It brings together data, rankings, and insights to help stakeholders navigate one of the most competitive areas of pharmaceutical litigation. The report is structured as follows:

1. **ANDA Statistics** – A 360° overview of ANDA cases, covering all parties, judges, and case activity between July 1, 2020, and June 30, 2025. Includes high-level trends, filing patterns, case outcomes, and patent analysis.
2. **Plaintiffs and Defendants** – Identification of the most active and best-performing

brand and generic pharmaceutical companies throughout the study period.

3 **ANDA Firms** – Comparative analysis of law firm performance and activity, including rankings of top firms representing Plaintiffs and Defendants.

4 **ANDA Attorneys** – Assessment of individual attorney activity and performance, highlighting the top performers on both the plaintiff and defendant sides.

5 **Local Counsel** – Review of the most active local counsel attorneys, with rankings for those representing both Plaintiffs and Defendants.

6 **ANDA Judges** – Evaluation of judges assigned to ANDA cases, with performance scores reflecting outcomes of adjudicated cases.

7 **Ranking Methodology** – Explanation of the scoring and ranking methodology, detailing how Activity, Success, and Performance scores were calculated for companies, attorneys, law firms, and judges.

Together, these chapters provide a **comprehensive resource** for stakeholders looking to benchmark performance, track trends, and make informed decisions in ANDA litigation.

Pedram Sameni
Founder and CEO

Disclaimer: *The data for this report was obtained from public sources including USPTO, PTAB, and PACER, as well as self-reported by attorneys on the Patexia website. Patexia has gone to great lengths to provide valid and accurate analysis based on this data. However, Patexia does not guarantee 100% accuracy nor take any responsibility for possible losses caused by the use of any information provided in this report.*

Executive Summary.

Between July 1, 2020, and June 30, 2025, a total of 1,373 ANDA cases were filed across U.S. federal courts. These cases engaged 137 judges, 471 companies, 1,574 attorneys (including 235 local counsel), and 200 law firms, underscoring the breadth and complexity of Hatch-Waxman litigation during the study period.

Case activity fluctuated year over year. In 2021, filings averaged 20.5 cases per month, gradually rising to 26.4 cases per month in 2024. The first half of 2025 points to renewed momentum, with filings climbing from 68 in Q1 to 87 in Q2. This shift suggests that ANDA litigation remains a highly active and competitive area, defined by ongoing patent expirations, product launches, and generic market pressures.

The 1,373 cases collectively involved 1,892 unique patents. Classification of these patents using the International Patent Classification (IPC) system identified 77 distinct IPC codes. As anticipated, the vast majority (90.39%) fell under A61K, covering pharmaceutical preparations. The remaining codes primarily addressed related areas such as the formulation, manufacture, preservation, and delivery of pharmaceuticals and therapeutic compounds.

This year's analysis covered every case filed during the five-year window, forming the foundation for our activity scores and rankings. To evaluate outcomes, we focused on the 965 cases concluded within the same timeframe, which enabled us to measure attorney and law firm performance beyond raw activity. As in prior editions, we highlight attorneys and firms that distinguished themselves either by volume of work or by outcome. Those ranked among the Top 250

in activity or performance are recognized with "Most Active" and "Best Performing" badges for 2025, continuing our tradition of celebrating excellence in ANDA litigation.

Out of the 471 pharmaceutical companies involved in ANDA litigation during the study period, 256 appeared as plaintiffs and 267 as defendants. Novartis was the most active overall, participating in 118 cases. On the defendant side, Aurobindo Pharma stood out with 113 cases, while Pfizer was the most active plaintiff, filing 109 cases in defense of its branded products. In terms of performance, Sun Pharmaceutical Industries Ltd. ranked first among defendants with a performance score of 99.47%. On the plaintiff side, Bristol Myers Squibb led with 97.89% and also secured the top overall performance score at 97.66%.

The data indicates that a select group of law firms maintains strong, long-standing relationships with major pharmaceutical companies on the brand side, consistently representing them across a significant number of cases. In contrast, generic pharmaceutical companies appear to diversify their representation, engaging a broader pool of law firms rather than concentrating on a few. Notably, several recently established firms have managed to gain visibility and secure partnerships with leading pharmaceutical players, despite their relatively small size and short track record.

Sterne, Kessler, Goldstein & Fox ranked as the most active firm in ANDA litigation over the five-year period, taking part in 80 cases split between 44 for plaintiffs and 36 for defendants. This level of involvement represented close to 6% of all cases filed between

July 2020 and June 2025. On the plaintiff side, Finnegan, Henderson, Farabow, Garrett & Dunner ranked first with 80 cases, while Winston & Strawn appeared most frequently for defendants, handling 62 cases. Looking at performance, Paul Hastings achieved the highest overall score at 98.23% and also led the plaintiff rankings with 98.59%. On the defense side, Troutman Pepper Locke LLP achieved the strongest results, reaching a 99.49% score.

At the attorney level, certain practitioners have shown consistent activity, representing clients in a substantial number of ANDA cases. Dennies Varughese of Sterne, Kessler, Goldstein & Fox ranked first as the most active attorney overall, handling 60 cases for both plaintiffs and defendants, and also led the plaintiff (Brand) category with 42 cases. On the defendant side, Dmitry V. Shelhoff of

Shelhoff Canfield & Chin was the most active, representing generics in 36 cases. In terms of performance, Jovial Wong of Winston & Strawn achieved the highest score among defense attorneys with 96.38%. On the plaintiff side, Bruce M. Wexler of Paul Hastings led with a score of 95.48%, while Wexler also ranked first in overall performance across both sides with 94.91%.

A total of 137 judges oversaw the 1,373 ANDA cases during the study period. Of these, 965 cases reached termination, with judges handling an average of 12 cases each, ranging from a single case to a maximum of 174. Judge scores, which measure the probability of a decision favoring the Plaintiff (Brand) in adjudicated cases, range from 0 to 1, with an average score of 0.67, indicating that, on average, brands had a 67% likelihood of prevailing in these cases.
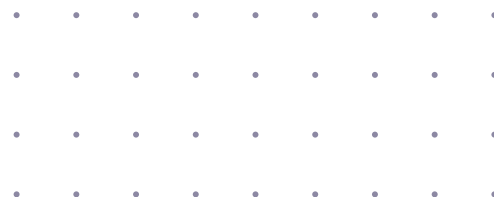
Appendix.

Appendix A: Sources of Data.

Data is the foundation and cornerstone of any data-driven analysis. Therefore, collecting data from quality sources and ensuring the integrity of that data is something we at Patexia take very seriously. We have sourced our raw data from a variety of reliable sources, including:

- Public Access to Court Electronic Records (PACER)
- Patent Trial and Appeal Board (PTAB) Database
- United States Patent and Trademark (USPTO) Patent Database
- US Patent Classification Database
- Self-reported by attorneys named on the case

For this release, we focused our analysis on the last five years, from July 1, 2020, through June 30, 2025, with an update as of July 7, 2025. While errors such as typos in legal documents are inevitable, cleaning and organizing attorney data presents additional challenges, particularly as attorneys change firms, may not update their information, and often use different variations of their names.

To address these challenges, our engineering team has implemented advanced machine learning and natural language processing techniques to accurately match various occurrences of the same name. To further minimize errors, we manually review suspicious matches and host profile pages for over 100,000 attorneys and agents, allowing them to directly review and add missing cases to our database.

Appendix B:
All ANDA Cases.

Please refer to the attached Excel file for a comprehensive list of all 1,373 ANDA cases filed from July 1, 2020, through June 30, 2025. The spreadsheet includes detailed information for each case, covering the following aspects:

• Case Number with a link to the case page on Patexia site
• Case Filing Date
• Case Decision Date (if terminated)
• Conclusion (if terminated)
• Judge(s)
• Court
• Case Title

Appendix C: Brand and Generic Pharmaceuticals.

Please refer to the attached Excel file for statistics related to all 471 companies involved in one or more ANDA/Hatch-Waxman cases filed during the study period. The spreadsheet provides the following information for each company:

- Company name with a link to Patexia page
- All Cases: Total number of ANDA cases for the period
- Defendant Cases
- Plaintiff Cases
- Overall Activity Rank
- Overall Performance Rank
- Defendant Activity Rank
- Defendant Performance Rank
- Plaintiff Activity Rank
- Plaintiff Performance Rank
- Overall Activity Score
- Defendant Activity Score
- Plaintiff Activity Score
- Overall Performance Score
- Defendant Performance Score
- Plaintiff Performance Score
- Overall Activity Rank 2024
- Overall Performance Rank 2024
- Defendant Activity Rank 2024
- Defendant Performance Rank 2024
- Plaintiff Activity Rank 2024
- Plaintiff Performance Rank 2024
- Top 3 law firms and the volume of cases for each

Appendix D: ANDA Firms.

Please refer to the attached Excel file for statistics related to all 200 law firms involved in one or more ANDA cases. The list excludes firms identified as local counsel. The spreadsheet includes the following information for each law firm:

- Law firm name with a link to Patexia page
- All Cases: Total number of ANDA cases for the period
- Defendant Cases
- Plaintiff Cases
- Overall Activity Rank
- Overall Performance Rank
- Defendant Activity Rank
- Defendant Performance Rank
- Plaintiff Activity Rank
- Plaintiff Performance Rank
- Overall Activity Score
- Defendant Activity Score
- Plaintiff Activity Score
- Overall Performance Score
- Defendant Performance Score
- Plaintiff Performance Score
- Overall Activity Rank 2024
- Overall Performance Rank 2024
- Defendant Activity Rank 2024
- Defendant Performance Rank 2024
- Plaintiff Activity Rank 2024
- Plaintiff Performance Rank 2024
- Top 3 clients and the volume of cases for each

Appendix E: ANDA Attorneys.

Please refer to the attached Excel file for statistics related to the 1,339 ANDA attorneys. The spreadsheet includes the following information for each attorney:

- Attorney name with a link to Patexia page
- Attorney's Title
- Law firm with a link to Patexia page
- All Cases: Total number of ANDA cases for the period
- Defendant Cases
- Plaintiff Cases
- Overall Activity Rank
- Overall Performance Rank
- Defendant Activity Rank
- Defendant Performance Rank
- Plaintiff Activity Rank
- Plaintiff Performance Rank
- Overall Activity Score
- Defendant Activity Score
- Plaintiff Activity Score
- Overall Performance Score
- Defendant Performance Score
- Plaintiff Performance Score
- Overall Activity Rank 2024
- Overall Performance Rank 2024
- Defendant Activity Rank 2024
- Defendant Performance Rank 2024
- Plaintiff Activity Rank 2024
- Plaintiff Performance Rank 2024
- Top 3 clients and the volume of cases for each

Appendix F: ANDA Local Counsel.

Please refer to the attached Excel file for statistics related to the 235 ANDA local counsel. The spreadsheet includes the following information for each attorney:

- Attorney name with a link to Patexia page
- Law firm with a link to Patexia page
- Attorney's current city
- Attorney's current state
- Overall Activity Rank
- Defendant Activity Rank
- Plaintiff Activity Rank
- All Cases
- Defendant Cases
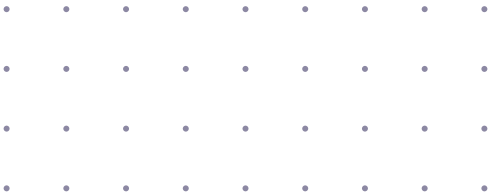- Plaintiff Cases

Appendix G: ANDA Judges.

Please refer to the attached Excel file for statistics related to the 137 ANDA judges. The spreadsheet includes the following information for each judge:

- Judge's name
- Total cases
- Total patents in all cases
- Judge's score
- Plaintiff score
- Defendant score

Appendix H: Best Performing and Most Active Badges.
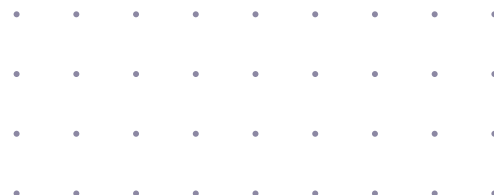
As part of our annual tradition, Patexia designs two categories of badges for Best Performing and Most Active Law Firms and Attorneys (Defendant, Plaintiff, and Overall). These badges are awarded to firms and attorneys ranked in the top 250 who choose to purchase the report. Concierge Members, however, automatically receive the badges if they are ranked among the top 250.

📞 **(310) 909-7611**   ✉ **info@patexia.com**

Contact Us.

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Disclaimer: The data for this report was obtained from public sources, including USPTO, PTAB, and PACER, as well as self-reported by attorneys on Patexia's website. Patexia has gone to great lengths to provide valid and accurate analysis based on this data. However, Patexia does not guarantee 100 percent accuracy, nor take any responsibility for possible losses caused by the use of information provided in this report.
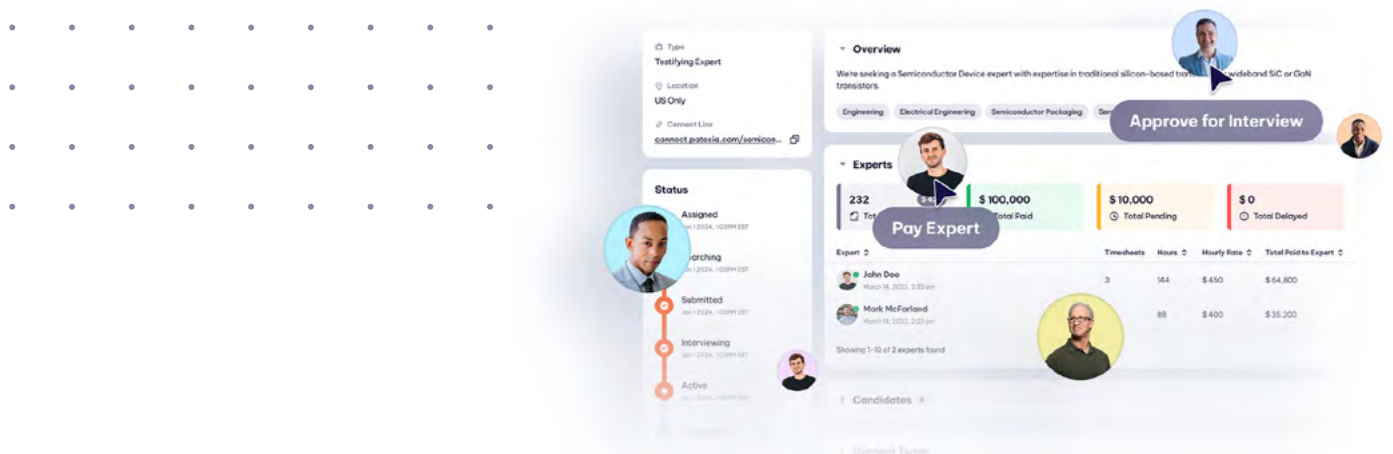
The fine print
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Our Solutions.

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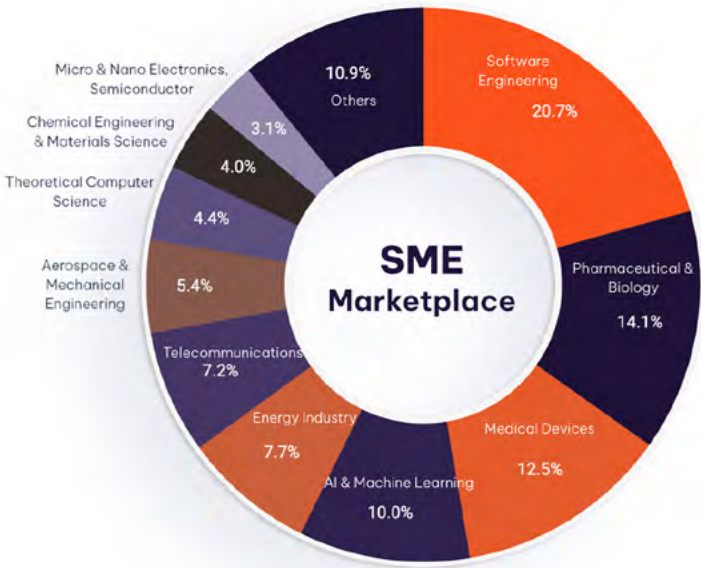### Access World-leading Expertise in every Field

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SME Marketplace

- Software Engineering 20.7%
- Pharmaceutical & Biology 14.1%
- Medical Devices 12.5%
- AI & Machine Learning 10.0%
- Energy Industry 7.7%
- Telecommunications 7.2%
- Aerospace & Mechanical Engineering 5.4%
- Theoretical Computer Science 4.4%
- Chemical Engineering & Materials Science 4.0%
- Micro & Nano Electronics, Semiconductor 3.1%
- Others 10.9%

> ❝ **What really stood out to me was how responsive the Patexia team was and how quickly they found candidates with the right credentials. The expert we worked with was key in helping us secure a favorable settlement by providing a crucial declaration for a patent challenge. The team's professionalism and understanding of legal dynamics, especially in handling billing, have made Patexia a trusted partner for expert witness sourcing."**

Douglas R. Nemec,
Head of Skadden's Intellectual Property Litigation Group.

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