Patexia





August 2023

ANDA Litigation 2023.

Intelligence Report

July 2018 — June 2023

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

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Introduction.

Embarking on a journey through the realm of ANDA litigation unveils a multifaceted landscape where pharmaceutical innovation, legal strategy, and regulatory intricacies intertwine. Within this domain, pharmaceutical companies navigate a dynamic space seeking approval to introduce generic versions of established drugs into the market. The intricate dance between brand and generic entities, coupled with the everevolving regulatory frameworks, weaves a vibrant tapestry of legal complexities. Patexia ANDA Litigation Intelligence 2023 serves as a guiding light, offering a comprehensive exploration of the trends, and prominent figures that mold the ANDA landscape. In this intricate arena, legal acumen and industry innovation converge, setting the stage for a deeper understanding of the challenges and opportunities that define ANDA litigation.

As we step into the realm of ANDA litigation for the year 2023, the landscape of life science litigation continues to shine as one of the most lucrative domains within patent litigation. While it may exhibit a lower volume in comparison to other patent litigation categories, the profitability per case for law firms often surpasses that of its counterparts. This economic dynamic not only fosters competition amongst law firms but also fuels the quest to attract premier legal talent, particularly for intricate litigations like ANDA and biosimilar cases. In this vibrant environment, law firms are compelled to make strategic choices to secure their stance. With the intention of avoiding conflicts, many opt to align themselves with one side of the equation – be it the representation of brand or generic pharmaceutical companies. While not an unyielding rule, the trajectory leans towards greater profitability when advocating for brand pharmaceutical entities.

What is New in ANDA Intelligence Report 2023?

In our latest edition, this year's report unveils an extensive array of enhancements and advancements that have been integrated to provide an even more comprehensive and insightful experience. Noteworthy updates encompass modifications to the ranking methodology, refining the precision and relevance of our assessments. A novel addition to this year's report is the introduction of the concept of attorney reviews, which serves as a valuable tool for discerning the nuances of legal prowess and professionalism which data alone cannot provide. Going beyond numerical evaluations, this allows us to shed

light on the remarkable attorneys who have garnered not only high rankings in terms of activity or performance but have also received positive reviews from co-counsels, opposing counsels and clients. This dimension adds a qualitative dimension to our analyses, offering a well-rounded perspective on the legal landscape. As we continually strive to enhance the depth and breadth of our insights, these strategic enhancements underscore our commitment to providing you with an even more insightful, accurate, and well-rounded view of the legal landscape within ANDA litigation.

Improved Ranking Methodology Using Machine Learning

ANDA litigation case outcomes are shaped by various factors, including parties, actions, judicial decisions, and expert testimonies. Evaluating individual success within this complex context is challenging. To address this, we utilize computational methods and machine learning algorithms to analyze individual performance across multiple cases. Our *Success Score* assessment employs a rigorous approach, isolating individual performance from external influences through advanced

machine learning and regression techniques. This ensures a fair evaluation of success in the litigation landscape. Practically, we use adjustments to recalibrate scores, considering diverse influencing factors. These adjusted scores are then used to calculate average scores for each party or representative across all their cases. This advanced methodology provides a more accurate and equitable evaluation of individual success in the intricate world of ANDA litigation.

Introducing Attorney Reviews

Patexia's commitment to comprehensive ANDA litigation evaluation aims to extend beyond numbers. With Patexia Attorney Reviews, introduced during our new website launch, we collect qualitative feedback from peers, co-counsels, and in-house counsel. These reviews cover vital aspects such as Efficiency, Responsiveness, Negotiation, Strategy, Experience in the Area, and Trial Capability that are often hard to quantify or derive from mere data. In-house and top 1,000 most active ANDA attorneys were invited to submit reviews until August 15. which were meticulously verified for authenticity. Anonymity options were offered to maintain transparency while respecting

confidentiality. This initiative provides valuable qualitative insights that complement quantitative data, offering a more holistic view for informed decisions. Positive industry feedback led us to incorporate the number of positive reviews in calculating the success score. This addition enhances our understanding of an attorney's expertise in the ANDA landscape, bolstering the accuracy of our assessments and spotlighting top attorneys. We express gratitude to participants for enriching our process with Patexia Attorney Reviews. Your contributions amplify our assessments' reliability, enhancing transparency and informed decision-making.

Highlighting Top Attorneys

We meticulously handpicked top-performing ANDA attorneys, focusing on the top 100 rankings from our reviewed list. This selection was cross-referenced for preci-

sion and followed by requests for individual interviews. With consistent questions, we explored their perspectives and methods, covering key qualities, workload man-

agement, client interaction, negotiation, trial preparation, and future trends. Transcribed responses, analyzed and incorporated as quotes or summaries, enriched the final feature. Each attorney's introduction includes their background, ANDA ranking, and a concise recap of reviewer feedback.

Our comprehensive approach blends rankings, reviews, and interviews to offer a well-rounded view of these leading ANDA attorneys, making Section 2 a good resource for understanding and engaging with some of the top talents in this competitive legal arena.



Pedram Sameni

Founder and CEO

What's in This Report?

The report content has been divided into the following sections:

- 1 ANDA Statistics: We provide a 360-degree overview of ANDA from all angles. We cover high-level statistics about ANDA, including all parties, judges, and cases, covering July 1, 2018, through June 30, 2023.
- 2 Reviewed Attorneys Spotlight: We introduce some of the top-ranking ANDA attorneys who have received positive feedback on the Patexia platform by their clients, co-counsel, or opposing counsel.
- 3 **Plaintiffs and Defendants:** We identify the most active and the best-performing brand and generic pharma companies over the period of our study.
- 4 **ANDA Firms:** We analyze the performance and activity of law firms, comparing and providing rankings for the top firms representing *Plaintiffs and Defendants*.
- 5 **ANDA Attorneys:** We review the performance and activity of ANDA attorneys, representing *Plaintiffs and Defendants*, comparing and providing rankings for top attorneys on each side.

- 6 **Local Counsel:** We review and identify the *most active local counsel*, representing Plaintiffs and Defendants, comparing and providing rankings for top attorneys on each side.
- 7 ANDA Judges: We look at the judges assigned to all ANDA cases for the period of this study and calculate their performance based on the outcome of their judgments.
- 8 Ranking Methodology: We explain our performance model and how we calculated the Activity, Success, and Performance scores and rankings for plaintiffs, defendants, their representatives, and ANDA judges.

As per our tradition for this and other intelligence reports, and to have a meaningful comparison, as well as compensating for the time required for each case from filing to completion (e.g., 6 to 36+months), we covered a period of five years, from July 1, 2018, through June 30, 2023. Appendix A lists all sources of data used for this report.

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.

Appendix.

Appendix A: Sources of Data.

Data is the foundation and building block of any data-driven analysis. Therefore, collecting that data from quality sources, and taking extra care in maintaining the data's integrity, is something that we, at Patexia, take very seriously. We have collected our raw data from many 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 limited the date range of our analysis to the last five years (July 1, 2018 through June 30, 2023).

While the possibility of errors such as typos in legal documents is inevitable, cleaning and organizing the attorney data is even more challenging as attorneys change firms, may not update their information, and often use different variations of their names.

Our engineering team has implemented sophisticated machine learning and natural language processing techniques to find the correct matches for various occurrences of the same name. To further minimize the errors, we not only review suspicious matches manually but also host profile pages for more than 100,000 attorneys and agents who can directly review and add missing cases to our database.



Appendix B: All ANDA Cases.

See the attached Excel file for the list of all 1,428 ANDA cases filed from July 1, 2018 through June 30, 2023. The spreadsheet covers the following information for each case:

- 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.

See the attached Excel file for the stats related to all 469 companies involved in one or more ANDA/Hatch-Waxman cases, filed during the period of our study. The spreadsheet covers the following information for each of the companies:

- · 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 Success Score
- Defendant Success Score
- Plaintiff Success Score
- Overall Performance Score
- Defendant Performance Score
- Plaintiff Performance Score
- Overall Activity Rank 2022
- Overall Performance Rank 2022
- Defendant Activity Rank 2022
- Defendant Performance Rank 2022
- Plaintiff Activity Rank 2022
- Plaintiff Performance Rank 2022
- Top 3 law firms and the volume of cases for each

Appendix D: ANDA Firms.

See the attached Excel file for the stats related to all 226 law firms that were involved in one or more ANDA cases. The list does not include firms that we identified as local counsel. The spreadsheet covers the following information for each of the law firms:

- 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 Success Score
- Defendant Success Score
- Plaintiff Success Score
- Overall Performance Score 2022
- Defendant Performance Score 2022
- Plaintiff Performance Score 2022
- Overall Activity Rank 2022
- Overall Performance Rank 2022
- Defendant Activity Rank 2022
- Defendant Performance Rank 2022
- Plaintiff Activity Rank 2022
- Plaintiff Performance Rank 2022
- Top 3 clients and the volume of cases for each

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Appendix E: ANDA Attorneys.

See the attached Excel file for the stats related to the 1,666 ANDA attorneys. The spread-sheet covers the following information for each of the attorneys:

- · 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 Success Score
- Defendant Success Score
- Plaintiff Success Score
- Overall Performance Score 2022
- Defendant Performance Score 2022
- Plaintiff Performance Score 2022
- Overall Activity Rank 2022
- Overall Performance Rank 2022
- Defendant Activity Rank 2022
- Defendant Performance Rank 2022
- Plaintiff Activity Rank 2022
- Plaintiff Performance Rank 2022
- Top 3 clients and the volume of cases for each



Appendix F: ANDA Local Counsel.

See the attached Excel file for the stats related to the 270 ANDA local counsel. The spreadsheet covers the following information for each of the attorneys:

- · 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.

See the attached Excel file for the stats related to the 153 ANDA judges. The spreadsheet covers the following information for each of the attorneys:

- 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 per our tradition, every year Patexia designs two categories of badges for Best Performing and Most Active Law Firms / Attorneys (Defendant, Plaintiff, and Overall). The badges are only provided to those firms and attorneys who are ranked in the top 100 and choose to purchase the report (Concierge Members will automatically receive the badges if they are ranked among the top 100).





















Contact

Established in 2010 with the goal of improving efficiency and transparency in the realm of intellectual property through the use of data, technology, and expert resources, Patexia is the leading network for IP professionals, boasting over 100,000 IP attorney profiles. The company offers a range of IP services through four distinct divisions: Patexia Connect (recruiting), Patexia Studies (Crowdsourced and traditional IP due diligence), Patexia Expert Witness, and Patexia Insights (IP reports and data). For further information, please contact us today.

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.

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Thank you for your purchase of the 2023 ANDA Litigation Intelligence Report. It is your support that enables us to spend the time, money, and precious thousands of hours needed to compile an annual report of this magnitude. We at Patexia sincerely hope this report brings value to your organization, and we welcome any thoughts or feedback you may have.

Our Solutions.



Insights

Use data-driven rankings to choose your next IP counsel. Leverage IP analytics for business development and competitive intelligence. Join the growing list of law firms and corporate clients who trust our research and reporting (<u>learn more</u>).



Expert Witness

Patexia uses data-driven tech to link law firms with top IP expert witnesses. By utilizing historical case data, we expedite the expert search, pinpointing the ideal match for your litigation needs and optimizing results for your IP cases (<u>learn more</u>).



Lateral Opportunities

Our experienced legal recruiters utilize sophisticated IP data analytics to assist law firms and attorneys in identifying the ideal lateral opportunities that correspond with their growth plans, geographical preferences, and areas of expertise (<u>learn more</u>).



Research Studies

Partner with our global network of 10,000+ experts from diverse industries for comprehensive research studies. We collaborate closely to understand your unique needs and goals, crowdsourcing most qualified experts to meet them (learn more).



Strategic Partnership

By promoting thought leadership, experience, and accolades to the digital community, we position you as thought leaders in IP law and showcase your expertise to corporate decision-makers, ultimately enhancing your brand and creating new business opportunities (learn more).

For questions or inquiries related to any of our offerings, please contact us at info@patexia.com or (310) 909-7611 or visit us at www.patexia.com