

THE AM LAW LITIGATION DAILY

Litigators of the Week: Truce With Generic Makers Over Rinvoq Sends AbbVie Share Price to New High

By Ross Todd

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Our Litigators of the Week are **Erica Andersen** and **Christopher Sipes**, co-chairs of the patent litigation group at **Covington & Burling**, and **David Frazier**, global vice chair of the intellectual property litigation practice at **Latham & Watkins**. They represented AbbVie last week as it secured the latest of five patent litigation settlements with generic makers set to protect the company's blockbuster immunology drug Rinvoq, which generated nearly \$6 billion in sales last year, until 2037. News of the deal, made public in an 8-K filing by the company, sent AbbVie share prices to a new high.

Lit Daily: What was at stake for AbbVie in these cases?

Christopher Sipes: AbbVie scientists developed the upadacitinib drug compound, as well as the specific solid state form of the compound and formulation leading to Rinvoq—a remarkable product that has helped numerous patients with a host of autoimmune conditions. AbbVie also spearheaded a massive research and development program for Rinvoq with over 45 clinical trials, leading to nine approved indications, with others in development. AbbVie has patents directed to these inventions, and the defendants attacked all



Credit: Gittings Photography/Courtesy photo

L-R: Erica Andersen and Christopher Sipes of Covington & Burling and David Frazier of Latham & Watkins.

of them, arguing non-infringement and invalidity. Our goal throughout the case was to showcase how remarkable these inventions are, and that the allegations made by the generic companies were simply not true.

How did this matter come to you and your firms?

Erica Andersen: Covington and Latham both have a long-standing history of successfully representing AbbVie in patent matters. For example, Covington (including Chris, me and our partners **Brianne Sullivan** and **Nicholas Evoy**) previously successfully represented AbbVie in matters related to their breakthrough oncology product, Imbruvica, at trial and on appeal, while Latham previously

successfully represented AbbVie in matters related to their top-selling immunology drug, Humira. Both Covington and Latham also have previously litigated patent cases in the immunology space, as well as cases involving drug compounds, solid state chemistry, pharmaceutical formulation and methods of treating patients.

David Frazier: AbbVie has successfully used a “virtual firm” model, bringing together the lawyers they think are the best fit for a particular matter. My colleagues **Herman Yue**, **Yi Sun** and I all have life sciences Ph.D. degrees, and we have all worked on AbbVie matters for years, so the client team knows our particular technical and legal strengths. They also know that we are well-acquainted with working on multi-firm teams. From our perspective, we were delighted to be a part of this combined team.

I’m new to the concept of immunology of drugs. Give me a quick tutorial on the technology behind Rinvoq, what it does in the body and what it has been approved to treat?

Sipes: Rinvoq is a ground-breaking, once-daily oral tablet that treats a variety of inflammatory diseases like rheumatoid arthritis, atopic dermatitis and Crohn’s disease, among others. It works by inhibiting enzymes called Janus kinases (JAKs), intracellular enzymes that play a pivotal role in signaling pathways that influence immune cell function across a range of autoimmune conditions. Prior to Rinvoq, many patients were forced to rely on biologic therapies, but these therapies are administered by injection or infusion, which can be painful and inconvenient. Many patients also fail biologics or become intolerant to them, which creates a significant need for better, more effective options. Rinvoq met this need and offered the promise of an oral, once-daily tablet that was highly effective, including for many patients that inadequately responded or are intolerant to TNF blockers. Rinvoq has been used to treat almost 160,000 patients in the United States since its approval in August 2019.

Who all was on your team?

Andersen: We had an absolutely incredible team. In addition to me and Chris, partners Brianne

Sullivan and Nicholas Evoy helped lead the charge, with of counsel **Eric Sonnenschein**, special counsel **Alex Trzeciak** and associates **Melissa Keech**, **Mike Morey**, **Cody Reeves**, **Laura Martin**, **Allyson Corigliano** and **Robert McMullen** playing critical roles. We had excellent paralegal support from **Kim Harkins** and **Elisabeth Crosby**. And our Delaware counsel, **Jeremy Tigan** and **Megan Dellinger** from **Morris, Nichols, Arsht & Tunnell** provided sage and spot-on advice throughout the litigation.

Frazier: In addition to myself, Herman Yue and Yi Sun directed the team and helped craft the legal strategy. Associates **Ramya Vallabhaneni**, **Kelly Welsh** and **Daniel Hemming** were instrumental in supporting daily interactions with opposing counsel and discovery issues, including multiple virtual depositions that occurred in the middle of the night due to differences in time zones. **Denise Laspina**, a former associate on the team, deserves a special mention, as she joined Latham after working at AbbVie as a summer intern in their legal department.

Here you were dealing with dozens of patents being asserted against five different companies’ proposed generic versions of Rinvoq. How do you divide up the team to deal with this kind of beast? By the defendant? By patent? By claim? And who was in charge of coordinating all the different moving parts?

Andersen: It was a challenging undertaking, to say the least! Covington took the lead for the patents directed to the upadacitinib compound and its solid state forms, which the defendants attempted to attack by raising interlinking invalidity arguments. Covington also led the charge for the patents directed to methods of treating each of the approved indications that were at issue in the case, which involve multiple disparate conditions across the fields of rheumatology, gastroenterology and dermatology—leading to a host of different issues. Latham took the lead on the formulation patents, which also relate to issues of pharmacokinetics and dissolution. At Covington, we had subteams focused on each type of technology to ensure we had expertise on each issue. Those subteams met weekly to do a deep dive into the substantive legal

and factual issues we were facing. We also, as you might imagine, had extensive coordination across subteams to ensure we understood the full picture and invention story, and to keep things consistent both factually and legally. Covington also had full weekly team meetings to maintain a high level of coordination, and to make sure nothing was falling through the cracks.

The two firms had a wonderful working relationship and coordinated frequently about cross-cutting issues like case narrowing, deposition strategy, contentions and experts. Latham and Covington jointly had weekly calls with the client to ensure a high level of coordination and that everyone was aligned on strategy.

Frazier: Both firms have extensive experience with litigating these types of cases. Our Latham team had worked previously on patents concerning formulations for Humira, so focusing on formulation here was a natural fit. While we had divided responsibilities by patent subject matter, we are all familiar with the issues that arise in litigation between brand and follow on pharmaceutical companies. I have tremendous respect for Chris and Erica, so we were able to talk things through on regular strategy calls with everyone contributing their good ideas. I'd like to think this is exactly what the client was trying to achieve in creating this "virtual firm" combination.

Who was working on the settlement piece of things?

Frazier: AbbVie's in-house counsel ran the negotiations with the defendants while we worked to litigate. AbbVie's in-house lawyers on this matter, **Linda Friedlieb**, **Lydia Nenow** and **Dan Hoang**, are experienced litigators themselves and operate as active members of the team. They were wonderful to work with on this and brought key strategic insights to the negotiations as well as the litigation.

What can other branded drug companies take from how AbbVie litigated these cases?

Sipes: Organization and litigating the case with an eye toward trial are critical. The case was large in scope, but we strategically pressed on and narrowed issues as time went on to show we were serious about taking the case through expert discovery and beyond.

Frazier: Bringing an experienced, trial-ready team to the litigation sends a strong signal to the opponents. The Rinvoq product is an exceptional drug that has helped many thousands of patients and reflects innovation on many levels. Our job as counsel is to distill the mountains of technical facts to explain in a compelling way how the inventions in the patents at issue came about and why they are important.

What will you remember most about this matter?

Andersen: Excellent lawyering, strategy and collaboration between firms leading to an incredible result for our client. Settlements like this don't often get the same press as trials or appeals—but this is a remarkable litigation outcome for AbbVie and is the result of years of behind-the-scenes work by numerous individuals.

Sipes: Seamless coordination both with our co-counsel and with in-house counsel. Rinvoq is a complex drug that called on a wide range of expertise within the company to develop, and AbbVie's in-house counsel did an extraordinary job bringing all those disparate parts together and coordinating the litigation effort so that we could tell that development story clearly and effectively. That is a main reason the case settled on such favorable terms once fact discovery was done.

Frazier: The daily collaboration with Covington and our AbbVie client team is what made this case a pleasure to litigate. It is also very gratifying to work with the talented AbbVie scientists who have made these inventions. It is a privilege to be able to advocate for the scientific and medical innovation story of a drug that has helped so many people.