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Litigators of the Week: J&J Beats Bayer's Injunction Aimed at Study Showing Reduced Death Risk in Rival Prostate Cancer Treatment

By Ross Todd
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Our Litigators of the Week are **Steve Zalesin** and **Jonah Knobler** of **Patterson Belknap Webb & Tyler**. They took the lead for Johnson & Johnson in a Lanham Act case where Bayer took aim at a study comparing the outcomes of patients using rival prostate cancer medications made by the two companies and J&J's statements about it. One point in particular Bayer took issue with was the claim that users of the J&J medication showed a "51% lower risk of death" through 24 months.

After Bayer filed suit February 23, the team raced to prepare to prepare witness and testimony for a two-day preliminary injunction hearing held before U.S. District Judge Dale Ho in Manhattan on March 16 and 17.

Last week, Ho denied Bayer's preliminary injunction bid, holding that the study was reliable and used widely accepted scientific methods and that J&J accurately represented its conclusions. Ho added that it was "not a particularly close call" whether the study's methodology was so flawed as to render its results unreliable.

Litigation Daily: What was at stake for J&J here?

Courtesy photos

Steven A. Zalesin (L) and Jonah M. Knobler (R) of Patterson Belknap.

Steve Zalesin: J&J's Erleada® and Bayer's Nubeqa® enjoy billions of dollars in annual sales. The ability to discuss a study that found a significant survival advantage for Erleada has obvious commercial value. But perhaps more important, Bayer sought to portray J&J's study, essentially, as junk science, putting at risk J&J's reputation in the oncology and broader medical and scientific communities. The court's ruling vindicated not just this study, but J&J's broader scientific integrity.

How did this matter come to you and the firm?

Jonah Knobler: J&J has been a valued Patterson Belknap client for decades. Our firm pioneered

competitor false advertising litigation under the Lanham Act via its work for J&J back in the 1970s. So, we were already on J&J's radar when J&J received Bayer's cease-and-desist letter. The client reached out to me to investigate and respond. We prepared a detailed response, which did not satisfy Bayer. Things proceeded quickly from there.

Who is on your team and how have you divided the work?

Knobler: We're fortunate to have a deep bench of exceptionally talented litigators, and we deployed those resources fully here. In the run-up to the hearing, our partner **Clint Morrison** identified our fact witnesses and worked with them to develop our story. Our partner **Amy Vegari** found four fantastic experts practically overnight and worked with them on their reports. I spearheaded our opposition brief, while Steve provided strategic guidance across the board. At the hearing, I gave our opening and examined both sides' statistical and regulatory experts. Clint examined our chief fact witness, who developed the study at issue, and Amy examined our medical and real-world-evidence experts; both also crossed Bayer scientists. Steve examined a J&J oncology witness, crossed Bayer's marketing witness and gave our closing. Our counsel, **Emma Ellman-Golan**, also crossed a Bayer fact witness. We were supported throughout by a brilliant group of associates: **Isaac Weingram**, **Maggie O'Neil**, **Faust Petkovich**, **Andrew Lief**, **Jillian Horowitz** and **Hibo H. Ali**.

This was an unusually fast-moving, high-stakes preliminary injunction fight involving science, marketing and the Lanham Act. When you first saw Bayer's complaint, what did you view as the single biggest risk to Johnson & Johnson—and how did that shape your strategy going into the hearing?

Zalesin: Bayer's initial court papers sought a response from J&J in just three days, and a hearing one week after the case was filed. That schedule would have afforded almost no opportunity to prepare a defense. Fortunately, the court allowed just the amount of time needed to identify witnesses and marshal the evidence we used to prove our case.

You resisted turning the hearing into a battle over whose epidemiology was better. How deliberate was the choice to argue that even if Bayer's criticisms were right, they still didn't meet the standard for injunctive relief?

Knobler: We knew from the outset that the reliability of J&J's research was at the heart of the case, and we focused primarily on defending the study at issue. But there was also a broader principle at stake: Scientists routinely disagree on cutting-edge research, and barring unusual circumstances, courts should not referee such disagreements. We chose very deliberately to emphasize that principle, which goes well beyond any one study.

Several Bayer witnesses acknowledged under cross that their critiques were hypothetical and not data-driven. Was that a key pivot moment for you in the hearing, or was it something you expected?

Zalesin: That was not a surprise to us. Bayer made a strategic decision to seek a fast hearing rather than obtain discovery of the data underlying J&J's study. In our opposition brief, in our opening statement and from our first cross-examination onward, we emphasized that Bayer's case was built on speculation, not evidence. That strategy ultimately proved dispositive.

Bayer never produced a single prescribing physician or patient who said they were misled. How important was that absence to your case, especially given Bayer's focus on supposed marketplace harm?

Knobler: The Lanham Act prohibits both literal falsehoods and statements that are true but misleading. In its complaint and other court papers, Bayer argued that J&J's statements about its research were literally false, not that they deceived their target audience of physicians. At the hearing, Bayer shifted its focus to how lay patients might construe J&J's statements, assuming they came across the statements at all. But there was no evidence that anyone, doctor or patient, was misled by anything J&J said. The court recognized this and analyzed Bayer's case through the lens of literal falsity—something Bayer could not prove.

On your side, you presented both practicing physicians and methodological experts. How did you decide who needed to testify live versus whose arguments were better left to the papers?

Zalesin: By agreement of counsel, the time at the hearing was divided equally: Each side had a total of 6.5 hours for opening statements, direct and cross-examinations and closing arguments. We budgeted our time with precision, recognizing we could not call every witness live or ask every possible question on cross. We did, however, identify one clear gap in Bayer's case, and we exploited it from the outset. Neither its employee witnesses nor its experts said in their declarations that they had ever prescribed the drugs at issue, and our cross-examinations confirmed as much. We called both a practicing urologist and a practicing oncologist—the types of specialists who treat prostate cancer—as witnesses at the hearing. Their testimony that the study would not have the impact Bayer claimed it would was unrebutted and helped drive the court's analysis.

Does this decision give pharmaceutical companies clearer guidance on how to communicate about clinical studies, or does that remain a narrow, fact-specific question?

Knobler: The decision reaffirms that bona fide scientific research enjoys First Amendment protection, and that statements about it should not be enjoined absent clear proof that the research itself is fraudulent or has been misrepresented. Pharma companies should take comfort in the decision insofar as their research is methodologically sound and accurately described.

What lessons can other defendants facing emergency injunction motions grounded in alleged data "misrepresentation" take from how this matter unfolded?

Zalesin: Defendants are often at a disadvantage because the plaintiff can take weeks to prepare its case—as Bayer did here—and force a response within days. Our firm's experience prosecuting and defending against emergency injunctions in similar matters enabled us to quickly identify and leverage the gaps in Bayer's case. We set clear strategic goals for the hearing, stuck to a plan and delivered on the key elements of our defense. That's typically a winning formula in these types of cases, and it certainly was here.

What will you remember most about this matter?

Zalesin: My first experience as lead trial counsel, more than 30 years ago, was defending J&J against a preliminary injunction in a false advertising case—in the same courthouse. So, this case was a bit of déjà vu for me, but with a different perspective this time around. What I will savor most is watching Jonah deliver our opening statement and examine key witnesses at his first PI hearing in federal court. I was fortunate to be given that opportunity as a young lawyer and am thrilled that Jonah and our partners Amy and Clint got the same chance to experience what I did early in my career. Our firm has a culture that encourages attorneys to embrace new challenges, and the decades-long relationship of trust between Patterson Belknap and J&J has enabled several generations of trial lawyers to flourish. The value of that partnership is immeasurable.

Knobler: This was a first for me in several respects, so there is a great deal I'll remember for the rest of my career. What I'll take with me most was the pleasure of working with this group of partners, counsel and associates: how vital each person's contributions were to the effort, given the extreme time pressure we faced; how selflessly and remarkably everyone rose to the occasion; and, most of all, how much camaraderie and joy everyone showed in meeting the challenge. When I left the courtroom after the hearing, I was beyond exhausted—but I couldn't stop smiling, because I was so proud to be part of our team and so proud of every team member's performance. I feel so fortunate to work with such talented lawyers and lovely human beings.