

THE  
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Litigators of the (Past) Week: Defending Against a \$290M Claim and Scoring a \$116M Win in Drug Patent Fight

By Ross Todd  
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**O**ur Litigators of the Week are **Mike Morin** and **David Frazier** of **Latham & Watkins** and **William (Bill) Raich** of **Finnegan, Henderson, Farabow, Garrett & Dunner**. They led a trial team that helped Sarepta Therapeutics emerge victorious as the counter-claimant in patent litigation against Nippon Shinyaku concerning treatment for Duchenne Muscular Dystrophy, a degenerative muscular disorder. After a one-week timed trial in Delaware federal court, jurors sided with Sarepta, finding the Nippon Shinyaku patent invalid, finding Sarepta’s patent valid and infringed and awarded Sarepta \$115.2 million in damages.

**Litigation Daily: Who is your client and what was at stake here?**

Mike Morin: We’re very proud to represent Sarepta Therapeutics, an innovative biotechnology company that focuses exclusively on rare diseases. This case involves breakthrough treatments for Duchenne Muscular Dystrophy, or DMD, which affects one in 3,600 male births. It’s



Courtesy photos

(Top L-R) Latham partners Mike Morin and David Frazier and Finnegan partner William (Bill) Raich. (Bottom L-R) Latham partners Michele Johnson and Rachel Blitzer

a truly devastating illness, which relegates boys to wheelchairs by their teens and, absent treatment, is usually fatal by their 20s.

In the late 1990s, Dr. Steve Wilton, a true pioneer, met some young boys afflicted with this

terrible disease and their families and made it his life's cause to help. After years of dedication, he came up with a revolutionary way to treat these sick boys using "antisense oligonucleotides," or ASOs. While not a cure, these ASOs delay muscular decline, slowing progression of the disease. Based on Dr. Wilton's work, Sarepta introduced three different ASOs to the market, one of which was at issue in this case. Our opponent, Nippon Shinyaku, or NS, came out with a competing drug, then sued Sarepta for patent infringement. Sarepta counterclaimed for infringement of Dr. Wilton's patents, and the case went to trial in late December 2024.

The stakes were huge, not only in terms of money (NS was seeking nearly \$300 million), but also in principle: NS literally put Dr. Wilton and his pioneering work on trial, arguing not only that his patent was invalid, but that he obtained it fraudulently and was driven by greed. We viewed this as a baseless and unfair attack on a true hero in the fight against muscular dystrophy, and were thus elated when the jury invalidated NS's patent, upheld Dr. Wilton's patent and awarded Sarepta \$116 million, fully vindicating Dr. Wilton and his work and resulting in a \$400 million reversal of fortune.

#### **How did this matter come to you and your firms?**

Bill Raich: Finnegan has represented Sarepta on a variety of contentious IP matters for over a decade and has particular experience with ASOs. Based largely on this pre-existing relationship, we were well situated to hit the ground running, and were delighted when Sarepta gave us the opportunity to do so. When the University of Western Australia, the owner of the patent asserted by Sarepta, joined the case, we were honored to represent them as well.

David Frazier: **Michele Johnson**, who chairs Latham's global litigation & trial department, has represented Sarepta for years, and recommended Mike and me for this case. While Finnegan was doing a terrific job, given the complicated nature of the case (with competing patents going both ways) and the stakes, Sarepta asked us to join forces. We were thrilled to do so, especially since Mike and I were partners at Finnegan before joining Latham a decade ago, and still have a terrific relationship with the firm and Bill in particular.

#### **How did you divide the workload, both pre-trial and during the trial?**

Frazier: Bill and I both have deep technical backgrounds in molecular biology, so we gravitate toward those issues. Mike has a keen ability to sharpen the technical arguments and present them in a way that motivates the jury.

In terms of the trial itself, Mike, Bill and I were co-leads. Mike opened and closed in both phases of the jury trial (liability then damages) and examined several key witnesses, including Dr. Wilton. Bill directed Sarepta's liability expert, crossed NS's primary inventor, and opened in the bench trial on inequitable conduct. I crossed both NS liability experts. **Michele Johnson** and **Rachel Blitzler** from Latham and Ryan O'Quinn and Yoonjin Lee from Finnegan also examined important witnesses. Other team members, including Latham's **Reba Rabenstein**, **Ernest Yakob**, **Will Orlandy**, **Tiffany Weston**, **Drew Roberts** and **Daniel Hemming** and Finnegan's Brian Kacedon, Kaitlyn Pehrson and Jameson Gardner, focused on witness preparation and preparing for and arguing pretrial motions, jury instructions and procedural issues. We also had outstanding support from our Delaware counsel—Jack Blumenfeld, Rodger Smith and Megan Dellinger of

Morris, Nichols, Arsht & Tunnell—and Sarepta’s terrific in-house team—Jessica Driscoll, Marc Evans, Ryan Brown, Cris Rothfuss and John Haberman—who supported us in every decision we made. It was a true team effort.

**This case had initially been teed up for trial in May 2024. What happened to push the trial date back to December?**

Raich: Judge Hall, who’d recently taken over the case, asked for argument at the May 2024 pre-trial conference on the meaning of one of the claim terms in Dr. Wilton’s patent. She’d recognized from reviewing the dueling summary judgment briefs that this term might require clarification. After deciding the issue in Sarepta’s favor, NS requested a continuation for additional expert reports and depositions. Once that had occurred, we reconvened for trial in December, and it was game on.

**You had a strict time limit to put on your case and the time to deal with objections was counted toward the party who lost the objection. How did that shape how you put on your case—and pursued and defended objections?**

Frazier: Time limits are common in patent cases. At first they seem hard, but then you realize they are helping you. For example, I crossed two sophisticated technical experts who would have happily debated for days, but I had to cut to specific points that would show the jury why their opinions didn’t hold water. Mike had an 11-minute cross of NS’s damages expert in which he established that: (1) if NS had won liability, he would have started with lost profits rather than a reasonable royalty, but made an about-face after Sarepta won; (2) NS’s attorney had asked the jury to disregard the court’s lost profits jury instructions in his opening; and (3) all

four “Panduit” factors for lost profits were met. Bill in particular had a big job in directing our one and only liability expert because, while time was short, there were important points we needed to get into the record. Despite the short allocations (10.5 hours per side for liability, 1.5 hours for damages), we had time to spare in both phases of trial, whereas NS ran out in both.

**What were your key trial themes and how did you drive them home with the jury?**

Morin: Our most important theme was that Dr. Wilton was the true innovator, and despite all the criticism from the other side, he was right. His patent application served as a blueprint that the rest of the field—including NS—followed. Every time his ideas were tested, the results were positive. NS argued that finding a working ASO from Dr. Wilton’s research was like trying to find a needle in a haystack. By closing arguments, we were able to demonstrate (including visually) that finding an ASO that didn’t work from within Dr. Wilton’s groundbreaking invention was like trying to find a piece of hay in a needle stack. And with spinning quarters, we demonstrated that the odds of all of those working ASOs occurring by chance would have been the same as flipping a coin and coming up heads 31 times in a row: 1 in more than 2 billion. That message ultimately carried over to invalidating NS’s patent as well. While there was no denying NS performed a lot of experiments, we used NS’s internal documents to show that it was following the work of Dr. Wilton and others from the start: like others, NS used Dr. Wilton’s patent as its blueprint.

**Mike, you handled the direct testimony of Dr. Steve Wilton, your lead fact witness. From what I’ve read about his cross-examination it sounds like opposing counsel was highly critical of the**

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**amount of time it took to get FDA-approved DMD drugs to market. How did you deal with that on redirect?**

Morin: Yes, the legal press picked up on the unfairness of NS's cross of Dr. Wilton, in which NS accused him of being financially motivated and not doing enough to help these sick boys, with one journalist calling it a "disgusting smear." I was surprised that NS attacked Dr. Wilton like that, not only because he is an undisputed pioneer (as even NS's inventor agreed), but also because he's an earnest, likable, humble man, who has spent his life helping sick children. On redirect, I asked him what he does with his royalties, and he explained that he sets some aside for his sick wife (who, tragically, has a presently incurable form of muscular dystrophy) and donates most of the rest to medical research. When I asked him how it felt being accused of not doing enough to help these sick children he choked up, explaining that while he's done everything he can, it haunts him that he can't do more. He then told the story of two young boys who died when a power outage caused their ventilators to stop working. There wasn't a dry eye in the courtroom.

**What can others take from how you litigated and tried this case?**

Raich: Litigation is all about streamlining when you get to trial. There are literally thousands of decisions that need to be made about case themes, witnesses, exhibits and everything else. This is where teamwork, mutual trust and clear

lines of communication really paid dividends, as the firms and our client worked together daily to put together the clearest, most compelling story that we could. Mike and David were fantastic about keeping us focused on our core themes and on watching the clock.

**What will you remember most about this matter?**

Raich: Working with the inventors, scientists, and clinicians who brought hope to children with DMD. As an attorney, it was such a privilege to get to know the people who spent years in the laboratory to develop these important therapies. It was particularly fulfilling to see this case through with Ryan O'Quinn and Yoonjin Lee, and to develop the client relationship for years prior with my mentor, Charlie Lipsey, and my colleague Alissa Lipton.

Frazier: This was the most emotional patent case I have ever been a part of. Both Dr. Wilton and the Sarepta witnesses testified about their personal connections to the patients suffering from DMD. It was an honor to present their story and advocate for the importance of what they have achieved. I was particularly proud of our associates and how they rose to the occasion.

Morin: I agree with David; it was a very emotional case. It was a privilege to represent Sarepta, whose entire mission is to fight rare diseases, and to spend time with Dr. Wilton, a true pioneer. I truly felt in the presence of greatness. And on that note, it was a great team effort, and a pleasure to reunite with Bill and the rest of the Finnegan team, who were fantastic.