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Litigator of the Week: Defending a 'Blockbuster' Antipsychotic Drug Patent During a Three-Week Zoom Trial

Barbara Mullin of Patterson Belknap Webb & Tyler fended off a generic drug maker's patent challenge to Janssen's antipsychotic drug Invega Sustenna which has more than $1.5 billion in annual sales. The win means nearly 10 more years of patent protection for the drug.

By Ross Todd
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The word "blockbuster" gets thrown around quite a bit when it comes to prescription drugs. But now, the blockbuster status of Invega Sustenna, an injectible antipsychotic drug used to treat schizophrenia and related disorders, is a matter of public record.

In an opinion unsealed this week, U.S. District Judge Claire Cecchi in Newark, New Jersey dubbed the drug a "blockbuster" while finding the sole patent that covers it valid. The judge noted the drug netted sales of $1.7 billion in 2019 alone for Johnson & Johnson subsidiary Janssen. The decision, which comes after a three-week bench trial held completely remotely in October 2020, turns back an attempt by generic maker Teva Pharmaceuticals to launch its own competing product.

It's a huge, dare we say blockbuster, win for J&J and its trial team, led by our Litigator of the Week, **Barbara Mullin** of **Patterson Belknap Webb & Tyler**. With the patent set to run until January 26, 2031, the decision translates to nearly a decade more protection.

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

Barbara Mullin: Our clients are Johnson & Johnson (J&J) subsidiaries Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, NV, the companies responsible for Janssen's long-acting injectable antipsychotic drug, Invega Sustenna®.

Courtesy photo

Barbara Mullin of Patterson Belknap Webb & Tyler.

Invega Sustenna is a blockbuster medicine, with over $1.5 billion in annual sales in the United States. The patent at issue in this case is directed to dosing regimens for the active ingredient in Invega Sustenna – paliperidone palmitate. The patent discloses a loading dose regimen and monthly maintenance dosing. These dosing regimens took over a decade to develop, and the inventors had to overcome substantial hurdles

and failures along the way. The resulting patent is currently the only patent that covers Invega Sustenna.

This case was a Hatch-Waxman patent challenge brought by Teva, which is seeking to introduce a generic version of Invega Sustenna in the United States. Teva did not contest that its product would infringe Janssen's patent, but it challenged the validity of the patent, arguing primarily that Janssen's invention was obvious.

We are grateful to have had the opportunity to show that Janssen's invention was as valid and innovative in the eyes of patent law as it is in the real world. Perhaps even more importantly, we are thankful that this victory enables J&J to reinvest in the development of new treatments, as the company uses revenue from blockbuster drugs like Invega Sustenna to fund research for future pharmaceutical development.

Who all was on your team and how did you divide the work?

The core team – the attorneys that played a significant role in presenting at trial – consisted of my partner, **Aron Fischer**, and my colleague **Andrew Cohen**, who is counsel at the firm. We were joined by an amazing team of associates: **Zhiqiang Liu**, **Jay Cho**, **Rob Quirk**, **Jeffrey Hughes**, **Maggie O'Neill** and **Meghan Larywon**. In addition, we were able to draw from the wisdom of my senior colleague **Greg Diskant**, who was incredibly supportive of our efforts. Our clients, **Jennifer Reda** and **Angie Verrecchio** of J&J, should also be given full credit. They were right there with us throughout the entire case and during trial, providing invaluable feedback and support.

The nature of this case, and the extent of expert witness testimony that was required, made it difficult to spread out witness examinations as widely among the team members as I would have liked. As a result, Aron, Andrew and I were the voice at the podium throughout the witness examinations. But everyone on the team made a significant contribution to our success.

Since this case was tried completely remotely in October 2020, how did you and your team handle witness preparation?

Witness preparation took on an added dimension in this case. Not only did we need to prepare witnesses as you normally would for giving testimony, we also needed to practice the logistics of remote testimony with them. Did they have a good internet connection? Were they able to see – and if needed, take control – over the documents being shown? Could their voice be heard clearly? Add to that a witness testifying from Belgium into what became a very late night for her to account for the time difference. It started to feel like we were all preparing to become television reporters.

I gather that you tried this case from the firm's offices in New York. What was your trial set-up like? How did you manage to put on your case to Judge Cecchi? And what sorts of precautions were you taking, given that this all occurred before the COVID vaccines were available?

We had a conference room set up in our offices that looked like a hybrid of a courtroom and a newsroom. We quickly learned that we needed a green screen behind the podium if we didn't want counsel to appear to disappear into the background. The camera shots from all active participants – the judge, witness, court reporter and counsel for each party – were projected onto a screen in front of us. And, although I was concerned that it might be distracting, once testimony started it all seemed quite normal, except for the occasional on-camera appearance of a dog or cat. Overall, I think the attorneys on both sides were incredibly impressed at the way Judge Cecchi and the District of New Jersey staff managed the trial – there were very few technical issues, and we did full trial days almost every day.

As for having trial in October 2020, it was pre-vaccine but also pre-Delta variant. At the time, infection rates were quite low in New York, significantly lower

than they are even now. For that reason, the team felt comfortable working together in person, with appropriate precautions. We wore masks when we weren't presenting to the court, we generally worked separately from our offices or in small groups, and we observed all social distancing protocols. And of course, anyone who was at risk or otherwise did not feel comfortable being at the office was welcome to work remotely.

Were there any elements of trying a case like this – an ANDA case focusing on the validity of a branded drug patent – that surprised you in how well they worked in the remote setting?

Yes, as I mentioned, trying this case by Zoom worked remarkably well. One of the biggest challenges in ANDA cases is explaining the disputed technical issues in a clear and understandable way. Before trial, I was concerned that it would be difficult to do that remotely. But, then, seeing the witness right there in front of you on your Zoom screen, instead of 20 feet or 50 feet away in a large courtroom, seemed to make it easier to pay attention to the scientific detail. It was also much more efficient for the witnesses and trial team. No one had to sit in a waiting room for days until it was time to testify. Although it may not work well in every case, it was surprisingly effective here.

Your firm has a long history of defending J&J and its subsidiaries at trial in patent cases. How did that experience play to your advantage in handling a case of this magnitude under these sorts of trying circumstances?

It certainly would have been more difficult to handle the case during the pandemic if we didn't have such a longstanding relationship with J&J. Having worked with our in-house counsel for many years, I didn't have to worry about building trust with them over Zoom. And there's a lot of institutional knowledge about how the company operates – how to find documents, where to get certain data, where do I find answers to certain questions – that would have been harder to develop during the time when everyone was working remotely.

As the judge points out the parties had very different views about your client's process to develop Invega Sustenna. Your client claimed "the extraordinary skill of Janssen's scientists" led to the project's success despite some initial unexpected setbacks. Teva argued "the alleged difficulties Janssen faced during development were avoidable." How were you able to persuade the judge that Janssen's description of the process was more credible?

It was really just a matter of laying out the story of the invention in detail by having the inventors explain what they did to develop the dosing regimen for Invega Sustenna. There's a principle in patent law – and also it's common sense – that you can't rely on hindsight to determine whether something that you know now would have been obvious in the past. When the inventors testified about the challenges they faced, the failed clinical trials, and the skepticism from outside experts, it became abundantly clear that nothing about the development of the dosing regimen for Invega Sustenna was easy or straightforward. The only way you could conclude that Janssen's various problems were avoidable would be to look at them with the 20/20 vision of hindsight.

What will you remember most about this matter?

I will always remember the people involved. For the inventors, they were not just doing a job. They were truly invested in trying to improve the lives of people suffering from debilitating psychotic illnesses, like schizophrenia. They have made a real difference to many – the patients, their families, and society as a whole that pays a stiff price because many patients with schizophrenia end up in the criminal justice system or institutional settings. I was honored to represent these inventors in the courtroom.