

Litigators of the Week: Rachel Krevans and Grant Esposito of Morrison & Foerster

By **Scott Flaherty**

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It may take years before a court has the final say on a law meant to promote market competition for so-called biologics—revolutionary but costly drugs derived from living cells or organisms. But with a win for Sandoz Inc., Rachel Krevans and Grant Esposito of Morrison & Foerster have set the standard.

In a March 19 ruling, U.S. District Judge Richard Seeborg in San Francisco refused to issue a preliminary injunction that would have blocked Sandoz from launching a "biosimilar" version of Amgen Inc.'s blockbuster biologic Neupogen, which is used for treating infections in cancer patients.

"This is what you want to do as a lawyer—work on cases like this," said Krevans.

The decision marks the first time a federal court has considered the law on biosimilars, and the first time a judge has ruled in favor of a biosimilar manufacturer. Seeborg's ruling also came just a couple weeks after Sandoz's drug, which it plans to market under the name of Zarxio, became the first ever biosimilar to secure approval from the U.S. Food and Drug Administration.

At the heart of the injunction fight was the Biologics Price Competition and Innovation Act of 2010 (BPCIA), which created an abbreviated path for bringing new drugs to market if they're deemed interchangeable with an already-approved biologic. In refusing to block Sandoz from marketing its biosimilar, Seeborg sided largely with the interpretation of the BPCIA put forth by MoFo's Krevans at a March 13 hearing.

Amgen's lawyers, led by Nicholas Groombridge of Paul, Weiss, Rifkind, Wharton & Garrison, had maintained that Sandoz was



required under the BPCIA's disclosure and dispute resolution provisions to share its application to sell the biosimilar, and to disclose its manufacturing process to Amgen. Seeborg rejected those arguments, ruling that Sandoz acted within its rights not to make the disclosures.

Amgen has already lodged a notice of appeal, teeing up the issues to the U.S. Court of Appeals for the Federal Circuit. An Amgen spokeswoman noted Thursday that Seeborg had entered final judgment and approved a stay, allowing for the appeal to go forward on an expedited basis.

For Krevans and Esposito, who had a long-standing relationship with Sandoz and supported Krevans in the briefing, the first-of-its-kind case has amounted to a crash course without a syllabus.

Amgen filed suit in October 2014, alleging patent infringement and unfair competition claims against Sandoz. But it didn't seek an injunction based on its interpretation of the untested biosimilars law until February 5, giving Sandoz's lawyers little time to prepare. Krevans said her team, including partner Erik Olson, poured enormous effort into preparing both for this month's injunction hearing and the inevitable appeal, bringing in appellate specialist Deanne Maynard to advise.

"Our strategy is one that is designed to win at the trial court and the appellate level," said Krevans.

It's too early to call the winner, but Krevans and her team are undoubtedly off to a good start.

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