GROUNDBREAKER

Rachel Krevans, Morrison & Foerster

Five years ago Congress enacted a law designed to speed up the development of biosimilar drugs. As the name implies, the Biosimilar Price Competition and Innovation Act was meant to strike a balance between rewarding the inventors of biologics, by giving them a 12-year marketing exclusivity period, while providing a path for makers of "highly similar" molecules—once that period expires and provided no patents are in play. Last year Amgen Inc. sued Sandoz for unfair competition, saying Sandoz had not complied with the law's complex disclosure process known as "the patent dance" before making plans to launch Zarxio, a competing version of Amgen's white blood cell stimulant Neupogen. U.S. District Judge Richard Seeborg and a split Federal Circuit panel agreed with Sandoz and a team led by Morrison & Foerster partner Rachel Krevans that biosimilar applicants are free to opt out of the patent dance and take their chances with an immediate patent suit. But the Federal Circuit also ruled that Sandoz had to wait six months from FDA approval before launching, a holding that MoFo and Sandoz are now seeking to challenge at the U.S. Supreme Court.

Rachael Krevans

You litigated this case at breakneck speed. It was less than a year from complaint to precedential appellate opinion. How do you gear up for a case like that?

You clearly have to put your team together with this in mind. We had a team that was a little more senior than I might have had on a case that was going to move more slowly. We could split up some tasks where there were really key things happening on parallel tracks at the same time. Another thing was to involve our appellate lawyers from the start, so that they are giving their input and we're getting the benefit of their analysis in real time as we're litigating the case in district court.

Of course, you do a lot of appeals. But you're saying that Deanne Maynard was involved as well?

That's exactly right. We had myself leading the team. We had Deanne at a point where the [issues] are just starting to crystallize. We also brought in Joe Palmore, her second in command in the appellate group. He is really expert on some areas of federal jurisdictional law and government agency procedures. We had

him come in and focus on some specific issues while we were still in district court. My partner Erik Olson was involved in the case from very early on. He is one of the best lawyers I know at thinking about and litigating injunctions. We had Grant Esposito, who is incredibly knowledgeable about the whole world of biosimilars and the ramping up of that industry, and what is and is not the same in the biosimilar world versus Hatch-Waxman. And then we had two very senior associates, one of whom was someone who is not a patent litigator at all but who has huge depth of experience in litigating unfair competition kinds of claims.

And you're all painting on a blank canvas. This was one of the very first interpretations of this brand new statute. So why is it important for biosimilar producers to have the option of engaging in the patent dance, rather than it being mandatory.

As we said in our appellate brief, the patent-exchange process could take up to 230 days ... just to commence patent litigation. Where an applicant values expedience over risk mitigation, the statute allows it to subject itself to immediate suit rather than engage in the process.

You got a great result before Judge Seeborg. Then during appellate briefing the Federal Circuit temporarily enjoined the launch of Zarxio.

Yes. In the end it delayed the launch by five months. But under the Federal Circuit's ruling, it's in essence a six-month injunction rule. Sandoz continues to believe that the Federal Circuit's ruling, which was different than the district court's on this point, will delay the launch of all biosimilars for six months, even when there are no patents in force. And that extra six-month delay materially delays the savings that are generated by biosimilars for the public, for the government, for patients. It's a hugely significant issue for both the developing biosimilar market and industry, and for the U.S. health care system.

The Federal Circuit did rule quickly, and Zarxio launched last fall. In terms of this particular case, is that what counted most?

We continue to think the six-month delay is wrong. We're obviously glad the drug is on the market now. But this drug is just the first of a big pipeline of biosimilars that are coming along, and it's an incredibly important issue for this country's health care system that there not be an extra six months of delay for every single biosimilar.

This is one of those cases where not only are billions of dollars on the line, but so are people's lives. Does that add a personal dimension to litigating the case for you?

I think it would add a personal dimension probably for most lawyers. This is about life-saving things. For me it's very personal because I have cancer. And my treatment's going very well. But when you actually have cancer and you know what these kinds of things cost—every two weeks I go in for an infusion and when I get the bill I think, "Thank god I have good health insurance."

Most cancer patients get treatments that are cocktails of different drugs, and some of them are off patent and some of them are not. When you see the bill, you don't have to know anything about patent law to know which ones are off patent and which ones are not. I'm not on this regimen anymore, but my original treatment regimen, the main ingredient was a biologic that is still on patent: $14,000 every two weeks.

Wow.

Yeah [laughs]. The world of biologic pricing is just so different from pharmaceuticals that it really raises the stakes on these things. And so many of these drugs are not for diseases where you're saying, "No, I don't need to take this." This is, "You need chemotherapy, or your tumors will grow and you'll die." So these are important drugs to make available to as many people as possible on a cost-effective basis.

What's your pitch to the Supreme Court on the six-month waiting period?

As we said in our petition for certiorari, and as [Federal Circuit] Judge [Raymond] Chen recognized in dissent, the majority effectively awarded sponsors "an extra-statutory exclusivity windfall" of 180 days more than Congress expressly granted. And as Judge Seeborg observed, if Congress had wanted to add six months to the [12-year] statutory exclusivity period, "it could not have chosen a more convoluted method of doing so."

— Scott Graham