

## TOP INTELLECTUAL PROPERTY LAWYERS 2020



### David I. Gindler

The patent on Rituxan, a medication used for treating rheumatoid arthritis and other ailments, expired a few years ago, but Gindler is still defending patents of specific dosages.

Rituxan is a biologic, which is different from a prescription drug like Lipitor, for example, is made from mixing chemicals and powders together, Gindler said.

“Biologics are a kind of drug which are made of and produced in biological material,” he explained. “They’re often produced in cells and they tend to treat very serious diseases like cancer, autoimmune diseases.”

A generic version of a biologic is a biosimilar, which can be more difficult to manufacture than mixing things.

“An example of a biologic is a specially-engineered antibody,” Gindler explained. “It’s really hard to make an antibody because they have three dimensions. They fold in funny, different ways. That’s hard to do.”

There’s also a clear definition from the U.S. Food and Drug Administration what a biosimilar must specifically achieve.

“When a company applies to make a biosimilar version of a biologic ... what they’re telling the FDA is that there is no clinically relevant distinction between what they propose to sell and what’s called the reference product,” Gindler said. “... So the FDA is basically the guardian of ensuring that what is being applied for in fact will produce the same clinical outcomes as Rituxan.”

But how biologics are used and the dosages for various treatments are also patentable, he said.

“These are commonly referred to as ‘method of treatment’ patents,” Gindler explained. “When a biologic gets approved by the FDA, the approval is to treat a particular disease according to a particular dosage regimen.”

In recent years, Gindler — representing Genentech Inc. and Biogen Inc. — has successfully fended off competitors such as Celltrion Inc. and Sandoz Inc., which filed applications with the FDA to market a similar biologic to Rituxan. *Genentech Inc. et al. v. Celltrion Inc. et al.*, 18-CV00574 (D. N.J., filed Jan. 12, 2018).

Gindler also has defended Genentech and Biogen in 25 petitions for inter partes review before the Patent Trial and Appeal Board for multiple patents involving the methods of using Rituxan.



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“All of the companies that wanted to make a biosimilar version filed challenges to the validity of many of the patents in the U.S. Patent [and Trademark] Office,” Gindler said.

He got successful outcomes in all but two of the proceedings. One of the two losses in patent claims was settled before appeal, Gindler added.

— Arin Mikailian