



Podcast Transcript

Biotechnology, Chemical and Pharmaceutical: Supreme Showdown

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Guest: Ron Kern, **Host:** Leeann Lee

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For questions and comments contact:



Ronald C. Kern Jr., Ph.D.

Partner

Philadelphia

T: +1.215.564.1669 | rkern@bakerlaw.com

Lee: It's been nearly one year since the Supreme Court issued a decision in the *Amgen v. Sanofi* case, a lawsuit that wound its way through the judicial system for nearly ten years, and finally had its day at the U.S. Supreme Court making waves in the biotechnology, chemical, and pharmaceutical communities. In BakerHostetler's inaugural Intellectual Property Perspectives Thought Leadership piece, the Intellectual Property Practice Group highlights myriad IP related topics that are at the forefront of industry developments, inspired by client wins and current challenges and trends. I'm Leanne Lee, and you're listening to BakerHosts.

On today's episode, we discuss the *Amgen v. Sanofi* Supreme Court decision, which found that *Amgen's* claims lacked enablement for attempting to cover an entire genus of antibodies. To provide us with insight into this topic, we have Ron Kern, a partner in the Intellectual Property Group at BakerHostetler. Ron is a member of the Biotechnology, Chemical, and Pharmaceutical team and focuses his practice on patent strategy in the life sciences, biotechnology, and pharmaceutical industries. Ron's practice encompasses the development of complex worldwide patent portfolios, patent prosecution, and due diligence investigations. He assists clients in developing and executing strategies to maximize IP protection and mitigate IP risks throughout all stages of the development and commercialization of biological products. Welcome to the show, Ron.

Kern: Thank you. It is great to be here.

Lee: To start us off, what exactly is enablement?

Kern: Sure. Enablement is one of the requirements that must be satisfied in order to obtain a patent in the United States. An enablement requires that a patent describe how to make and use the claimed invention, so that somebody reading your patent can basically copy what you've done.

Lee: Now, this case was closely watched by those in the pharmaceutical industry, and it was the first time in nearly 100 years that the Supreme Court addressed enablement. Why was this case so important?

Kern: I think it was a combination of timing, the particular claims at issue, and the nature of the invention. So, over the years, the Federal Circuit has developed a substantial body of case law around the enablement requirement. According to the Federal Circuit, a patent application must describe to those of skill in the art how to make and use the claimed invention without undue experimentation. And the undue experimentation is really the key to the enablement inquiry. The Federal Circuit established a list of factors called the Wands factors that are used to determine if undue experimentation would be needed. In finding that the claims at issue in *Amgen's* patent lacked enablement, the Federal Circuit stated that the patent did not enable the full scope of the claims without undue experimentation. That full scope language is what was at issue at the Supreme Court.

Lee: You mentioned the particular claims at issue and the nature of the invention. Can you tell us a little bit more?

Kern: The antibodies in this case are therapeutically important. These antibodies are involved in the regulation of cholesterol levels and can be used to treat individuals with high cholesterol. Both *Amgen* and *Sanofi* market antibodies to treat high cholesterol. However, *Amgen's* claims were not directed to a specific antibody or the specific antibody that *Amgen* is marketing. Rather, they were functional genus claims, meaning that they described what the antibody does rather than what the antibody is. *Amgen's* patent claims covered an entire genus or class of antibodies that specified where the antibody binds to its target, rather than what the amino acid sequence of the antibody is.

Lee: Now, you mentioned that the Federal Circuit has developed a substantial body of case law regarding the enablement requirement. Did the Supreme Court follow the Federal Circuit's approach in finding that *Amgen's* claim lacked enablement?

Kern: Interestingly, no, the Supreme Court did not rely upon or even mention a single Federal Circuit decision. Instead, the court relied upon its own prior body of case law, which dated all the way back to 1853 and involved technologies such as telegraphic communications, incandescent lamps, and wood veneering glues. It did not rely upon a single case involving an antibody or life science.

Lee: In the Supreme Court's view, what exactly is required to establish enablement?

Kern: The Supreme Court declined to place any bright line rules on what is needed to satisfy the enablement requirement. The court simply stated that the more a party claims, the more it must enable. Therefore, it is going to be a case-by-case basis to determine whether or not a patent is enabled, and it will come down to the complexity of the invention and the underlying technology.

Lee: Fantastic. And I have just one more question for you. It has been almost one year since the Supreme Court's decision. So, how have things changed since then?

Kern: Well, the Supreme Court did not shut the door on genus claims per se. But it is clear that courts are really going to continue to scrutinize these claims. So, applicants are trying to develop different ways to claim these broader genus claims. One way of doing so is a means plus function claim, and the United States Patent and Trademark Office just recently, within the past couple of days, issued a memorandum for the patent examiners on how to examine those types of claims. The Patent and Trademark Office also released new enablement guidelines, and in those enablement guidelines they state that they will continue to follow the Federal Circuit's Wands factors when evaluating undue experimentation, and they will do so regardless of the technology. And the Federal Circuit has addressed a couple of cases since the Supreme Court decision, and in those cases, they have mentioned that nothing has changed in view of enablement. So, we have to try to find new ways to claim these genus claims, but in terms of what the Federal Circuit is looking at, nothing's really changed.

Lee: This has been a great conversation. Thank you for your time, Ron.

Kern: Thank you.

Lee: If you have any questions for Ron, his contact information is in the show notes. For more information on BakerHostetler's Intellectual Property Perspectives Thought piece, we encourage you to download the document on bakerlaw.com. As always, thanks for listening to BakerHosts.

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